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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

VINCENT DANG, WARREN DRABEK, Plaintiffs, vs. AMARIN CORPORATION PLC, JOHN F. THERO, MICHAEL W. KALB, and JOSEPH T. KENNEDY, et al. Defendants.	No. 3:21-cv-19212-GC-TSB CLASS ACTION AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

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This is a federal securities class action on behalf of all persons and entities that purchased or otherwise acquired Amarin Corporation plc ("Amarin" or the "Company") American Depositary Shares ("ADSs") between September 24, 2018 and April 12, 2021, inclusive (the "Class Period"), and were damaged thereby (the "Class"), against: (i) Amarin; (ii) former President and Chief Executive Officer ("CEO") John F. Thero ("Thero"); (iii) former Senior Vice President ("SVP") and Chief Financial Officer ("CFO") Michael W. Kalb ("Kalb"); and (iv) former Executive Vice President ("EVP") and General Counsel Joseph T. Kennedy ("Kennedy") (collectively "Defendants"), for violations of §§10(b), 20(a), and 20A of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b), 78t(a), and 78t-1, and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

Lead Plaintiff 1199SEIU Health Care Employees Pension Fund (the "Pension Fund") and Plaintiff Warren Drabek (together, "Plaintiffs"), on behalf of itself and the Class, by and through its counsel Robbins Geller Rudman & Dowd LLP ("Counsel"), alleges the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Plaintiffs' information and belief are based on, among other things, the independent investigation of Counsel. This investigation includes, but is not limited to, a review and analysis of: (i) public filings by Amarin with the U.S. Securities and Exchange Commission ("SEC"); (ii) public filings and materials concerning Amarin with the U.S. Food and Drug

Administration ("FDA"); (iii) public filings and materials concerning Amarin with the U.S. Patent and Trademark Office ("USPTO"); (iii) transcripts of Amarin senior management's conferences with investors and analysts; (iv) press releases and media reports issued about and disseminated by the Company; (v) analyst reports issued about Amarin; (vi) public transcripts, filings, and other materials from *Amarin Pharmaceuticals, Inc. et al. v. Hikma Pharmaceuticals USA Inc. et al.*, No. 2:16-cv-02525 (D. Nev.) and related actions; and (vi) other public information and data regarding the Company.[1]

I. SUMMARY OF THE ACTION

1. Defendants defrauded investors and enriched themselves by tens of millions of dollars by capitalizing on a window wherein Amarin's ADSs traded at artificially inflated prices. In this window, which lasted throughout the Class Period from September 24, 2018 to April 12, 2021, Defendants knew or recklessly disregarded – but did not disclose to investors – that Amarin's sole product, VASCEPA® (icosapent ethyl) ("Vascepa"), would soon lose its patent protection, sending Amarin's inflated share prices into a nose dive. Rather than disclose this stark future to investors, Defendants instead sold vast portions of their personal shares

[1] *Amarin Pharmaceuticals, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 2:16-cv-02562 (D. Nev.) was consolidated with *Amarin v. Hikma*, No. 2:16-cv-02525 and *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 2:16-cv-02658, and the consolidated case is herein referenced as the "ANDA Litigation."

of Amarin ADSs for enormous profits, with the Individual Defendants pocketing a total of over $83 million.

2. At the start of the Class Period, Amarin was a small, single-product pharmaceutical company. Its product, Vascepa, is purified fish oil. In particular, it is comprised of 96% eicosapentaenoic acid ("EPA"), one of two primary omega-3 fatty acids commonly extracted from fish. Pure EPA has long been known to lower triglycerides and lipoproteins in the blood without increasing cholesterol, which therefore decreases the risk of cardiovascular events, strokes, and other negative medical outcomes. Vascepa was the first drug consisting of purified EPA introduced to the U.S. market.

3. Although Vascepa purportedly represented a new product in the U.S., Amarin did not invent purified EPA or discover any of its positive medical characteristics. Years before Vascepa launched in 2013, a Japanese company called Mochida Pharmaceutical Co., Ltd. created a purified EPA product called Epadel. Several studies of Epadel in the early 2000s demonstrated the positive effects and outcomes associated with Epadel, including lower triglycerides, lipoproteins, cholesterol, and cardiovascular risk. Defendants knew about these studies and referred to them to promote Vascepa during its clinical trials and leading up to its launch.

4. Since Vascepa was the first purified EPA introduced in the U.S., the FDA classified it as a new chemical entity ("NCE") and therefore granted it five years of regulatory exclusivity. During this time, Amarin's competitors could not apply to the FDA to sell generic versions of Vascepa without conducting their own research.

5. But since Amarin did not invent the product or discover any new use for it, Vascepa was not entitled to patent protection. Patents provide a much longer period of exclusivity for pharmaceutical products – 20 years – but must pass a higher bar and demonstrate that the product was useful, novel, and not obvious in light of, among other things, any domestic or foreign publication.

6. Amarin applied for patents anyway, and the U.S. Patent and Trademark Office rejected the application four times because Vascepa was deemed obvious in light of various studies concerning Epadel and other existing omega-3 fatty acid products. After several rejections, Amarin suddenly switched gears and incorrectly claimed Amarin had discovered the "unexpected result" that Vascepa lowered levels of a particular lipoprotein, called apolipoprotein B ("ApoB"). In reality, a pre-existing study in Japan entitled *Eicosapentaenoic Acid Effect on Hyperlipidemia in Menopausal Japanese Women. Obstet. Gynecol*. 96:521-8 (2000) by Kurabayashi, *et al*. ("Kurabayashi" or the "Kurabayashi Study") had already demonstrated that pure EPA not only lowered triglycerides, but also resulted in a statistically significant decrease in ApoB levels. Defendants were aware of the Kurabayashi Study well

before they applied for the patent, and years prior they cited to it as evidence to investors that Vascepa could treat patients with elevated triglycerides.

7. Defendants nevertheless concealed the Kurabayashi Study from the USPTO by burying it amongst hundreds of other studies provided to the patent examiner, while they misleadingly argued that these studies contained "no evidence of a reasonable expectation of success or any predictability with respect a reduction in apoB." Relying on these assertions, on July 26, 2012, the USPTO finally granted Vascepa's patents, citing its incorrect belief that "[t]he prior art is either silent or teaches that there is no statistically significant change in Apo-B levels" for patients taking pure EPA.

8. After the patents were issued, competitors had to wait until four years into the NCE exclusivity period before they could challenge the validity of the patents by filing an Abbreviated New Drug Application ("ANDA"). If a competitor challenges the validity of a patent, the patent holder can file suit in federal district court for patent infringement. On July 26, 2016, on the first day challenges were allowed, three of Amarin's competitors filed applications to sell generic versions of Vascepa, challenging the validity of Vascepa's patents. In turn, Amarin initiated patent infringement actions against all three competitors.

9. Meanwhile, Amarin launched a clinical trial called Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial (REDUCE-IT®)

("REDUCE-IT"), which was designed to dramatically increase the scope of patients indicated for Vascepa by showing the drug reduced the risk of cardiovascular events in high risk patients, a population comprising one fourth of the U.S. population. Years prior, in 2007, a paper by Yokoyama *et al*. called the *Japan EPA Lipid Intervention Study* ("JELIS") had already demonstrated that Epadel reduced cardiovascular risk in a statistically significant way. REDUCE-IT sought to replicate this study. The REDUCE-IT study lasted for approximately six and a half years, and Amarin announced on September 24, 2018 that it had met its primary endpoint. Like JELIS before it, REDUCE-IT showed a decreased risk for cardiovascular events in high-risk patients. In reaction to this news, Amarin's share price skyrocketed, quadrupling its value overnight.

10. Rather than temper expectations or disclose to investors that Vascepa's patents could soon be invalidated, Defendants did the opposite. Defendants made material misrepresentations, claiming, for example: that Vascepa would "be a significant blockbuster and help millions of patients reduce cardiovascular risk on top of standard-of-care statin therapy"; the "REDUCE-IT results position Vascepa to become a blockbuster"; and "Vascepa total net revenue will grow to reach multiple billions of dollars." Thero claimed they were "confident in the results" of the pending ANDA Litigation, and thus continued to claim they would be able to generate revenue

from those patents for years, with Kennedy reminding investors they "go out to 2030." Investors bought into these assurances and Amarin's share price remained inflated.

11. But Defendants themselves did not believe what they were selling to the market. As hordes of investors purchased Amarin ADSs at higher and higher prices, Defendants systematically unloaded their personal shares to their unsuspecting constituents. ***On the very same day Amarin announced the REDUCE-IT results, Kalb and Kennedy together immediately unloaded over a million shares and pocketed a $12 million windfall for themselves***.

12. Over the course of the Class Period, as investors continued to buy into the future at Amarin, the Individual Defendants continued to sell off their holdings. Each Individual Defendant accumulated generational wealth beyond most investors' wildest dreams. In ADS sales alone, CEO Thero sold 24% of his shares for $36.8 million, CFO Kalb sold 53% of his shares for $9.8 million, and General Counsel Kennedy sold 83% of his shares for $36.5 million. Defendants would not have dumped such large portions of their holdings if they truly believed Vascepa would grow to be a "multiple-billion-dollar opportunity" as they had led investors to believe.

13. And Defendants were fully aware of the vulnerability of Vascepa's patents. Vascepa was Amarin's only product and the Company's only source of revenue, so they were acutely aware of the fragility of the patents and the threat posed by the pending ANDA Litigation. All Defendants attended conference calls with

investors and spoke about the progress of the litigation and the strength of the patents throughout the Class Period. Thero was President of Amarin throughout the course of the patent prosecution and Kennedy has publicly admitted he "[l]ed Amarin's strategy" that led to the wrongful issuance of Vascepa's patents. Armed with this inside knowledge, Defendants sold their shares while they disseminated false and misleading statements to the market to convince others to buy.

14. Amarin's share price came crashing back to reality over the course of three disclosures in 2020 and 2021. First, on March 30, 2020, Chief Judge Miranda M. Du in the District Court for the District of Nevada invalidated the Vascepa patents, citing the "overlooked" Kurabayashi Study as a basis for her decision. Then, on September 2, 2020, the Court of Appeals for the Federal Circuit heard Amarin's appeal and ultimately affirmed Judge Du's opinion the next day. Finally, on April 12, 2021, Thero suddenly left the Company under suspicious circumstances, revealing to investors he had been culpable for the Company's downfall, and that the Company had given up on recovering its U.S. patents for Vascepa.

15. As summarized above and detailed further herein, the disclosures of the truth about Vascepa and its patents had a devastating impact on the Company's shareholders, and the value of Amarin's ADSs collapsed by more than 70%, inflicting substantial damage to Plaintiffs and other members of the Class.

II. JURISDICTION AND VENUE

16. The claims asserted herein arise under §§10(b), 20(a), and 20A of the Exchange Act, 15 U.S.C. §§78j(b), 78t(a), and 78t-1, and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act, 15 U.S.C. §78aa.

18. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and §27 of the Exchange Act, 15 U.S.C. §78aa, because Amarin's U.S. headquarters were located within this Judicial District throughout the Class Period, and Defendants conducted substantial economic activity in the Judicial District. As such, substantial acts in furtherance of the alleged fraud have occurred in this Judicial District.

19. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiffs

20. Lead Plaintiff 1199SEIU Health Care Employees Pension Fund is a multi-employer Taft-Hartley defined benefit plan providing benefits to working and retired healthcare industry workers and their families in New York City and surrounding areas. The Pension Fund purchased Amarin ADSs during the Class

Period, and suffered damages as a result of the violations of the federal securities laws alleged herein, as detailed in the attached certification. Exhibit A.

21. Plaintiff Warren Drabek purchased Amarin ADSs during the Class Period, and suffered damages as a result of the violations of the federal securities laws alleged herein, as detailed in the attached certification. Exhibit B.

B. Defendants

22. Defendant Amarin is a biopharmaceutical company with its headquarters located in Dublin, Ireland and its U.S. office located at 440 Route 22, Bridgewater, New Jersey, 08807. Amarin shares traded on the NASDAQ under the symbol "AMRN" during the Class Period.

23. Defendant Thero was President, CEO, and a director at Amarin throughout the Class Period. He was the Company's CFO starting in November 2009, President and CFO starting in November 2010, and became President and CEO in January 2014. Amarin announced Thero's retirement on April 12, 2021, and he retired in August 2021.

24. Defendant Kalb was SVP and CFO of Amarin throughout the Class Period. He held those titles from June 2016 until June 2022.

25. Defendant Kennedy was EVP and General Counsel of Amarin throughout the Class Period. He acted as Amarin's General Counsel throughout his

tenure, from December 2011 until July 2021. The Company announced his retirement on April 29, 2021.

26. Thero, Kalb, and Kennedy are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions at Amarin, possessed the power and authority to control the contents of Amarin's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors.

27. Each of the Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the investing public, and that the positive representations and omissions being made were then materially false and/or misleading.

IV. FACTUAL ALLEGATIONS

A. Amarin and Vascepa, Its Only Product

28. Amarin is a relatively small pharmaceutical company and had less than 500 employees at the start of the Class Period. Although it is headquartered in

Ireland, it conducted most of its business during the Class Period from its U.S. offices in Bridgeport, New Jersey.

29. Amarin's only product is Vascepa, which is purified EPA, a naturally occurring omega-3 fatty acid found in fish oil. Amarin launched Vascepa as a prescription drug in the U.S. in 2013. Since that time and throughout the Class Period, Vascepa was Amarin's only product. In fact, in July 2019 – years after the launch of Vascepa – an investment analyst asked Thero whether Amarin intended to develop or acquire different products to add to the Company's portfolio. In response, he said such acquisitions were "not our top priority," explaining "the focus is approval and successful launch" of Vascepa.

30. Because Vascepa was Amarin's only actual or prospective product, Amarin executives exclusively focused on issues concerning the drug in their day-to-day work. Indeed, all current and prospective revenue depended upon Vascepa. As a result, every filing with the SEC and conference call with investors focused on the Company's effort to maximize the profitability of the drug, including label expansion, market awareness, and fending off competitors. Amarin executives frequently claimed to have expansive knowledge regarding every detail about Vascepa and its financial prospects. For example, Thero told investors: "Amarin has always been deeply entrenched in research on omega-3s." And when the ANDA Litigation arose, Defendants acknowledged the Company's focus on the outcome, with Kalb saying,

"we are prioritizing our spending to emphasize the following: winning the patent litigation appeal."

B. The History of EPA and Other Omega-3 for Medicinal Use

31. Amarin did not invent the use of fish oil or omega-3 fatty acids for medical purposes. Fish oil is comprised primarily of two omega-3 fatty acids, EPA (the only active ingredient in Vascepa) and docosahexaenoic acid ("DHA"). The compounds contained in fish oil have long been thought to help control chronic diseases such as lupus, eczema, and rheumatoid arthritis, while also helping to prevent catastrophic medical events, including heart attacks and strokes. The Greek physician Hippocrates wrote about using dolphin liver oil to treat skin conditions well over 2,000 years ago. Early Shetland islanders are reported to have used cod liver oil to treat "old pains"; shark-liver ointment was being used in the 1700s to treat rickets; and the English physician Thomas Percival had cod liver oil entered into the 1771 British Pharmacopoeia for the treatment of arthritis.

32. The modern interest in omega-3s dates back to a Danish study on the Inuit population of Greenland in the 1970s, when researchers Hans Olaf Bang and Jørn Dyerberg found the Inuits had lower rates of coronary heart disease than Danish populations. The researchers suggested that the improvement in cardiovascular health was due to the Intuits' omega-3-rich diet comprised largely of oily fish, algae, and cod liver.

33. In the 1990s, clinical studies verified the benefits of EPA and DHA, demonstrating omega-3 fatty acids lower the concentration of lipids and lipoproteins in the blood. Lipids are fatty water-soluble compounds that travel throughout the body in the bloodstream. Triglycerides are the primary lipids derived from natural fats and oils. Lipoproteins are conglomerate particles in the blood containing lipids and proteins. The proteins in lipoproteins are called apolipoproteins, of which there are various types with different functions commonly referred to as ApoA, ApoB, ApoC, etc. ApoB, which is of particular interest in this case, moves cholesterol throughout the body. There are two different types of cholesterol: "good" cholesterol called high-density lipoprotein cholesterol ("HDL-C"), and "bad" cholesterol called low-density lipoprotein cholesterol ("LDL-C"). People with elevated levels of triglycerides, ApoB, and LDL-C are at a higher risk for heart attacks and strokes.

34. Vascepa is not the first omega-3-fatty acid-based prescription drug in the U.S. In 2004, Woodward Pharma Services, LLC launched "Lovaza," an EPA/DHA combination product that treats patients with elevated triglycerides who are at risk for catastrophic cardiovascular events.

35. Amarin was also not the first company to purify EPA and market it as a prescription drug. In 1990, over two decades before the launch of Vascepa, a Japanese company called Mochida Pharmaceutical Co., Ltd. launched a purified EPA product in Japan called Epadel. Amarin has publicly acknowledged that Epadel

contains "the same active ingredient" as Vascepa, meaning it is pharmacologically equivalent. Various studies of Epadel in Japan have confirmed the unique medical benefits associated with treatment from purified EPA, which expand beyond the advantages associated with treatment by EPA/DHA combination products. For example:

(a) in 2000, a study by Mori et al. entitled *Purified eicosapentaenoic and docosahexaenoic acids have differential effects on serum lipids and lipoproteins, LDL particle size, glucose, and insulin in mildly hyperlipidic men* ("Mori") compared the effects of pure EPA with pure DHA on patients' cholesterol levels. The study found that "DHA significantly increased HDL cholesterol, whereas EPA significantly lowered both total cholesterol and apolipoprotein (apo) A-1 concentrations";

(b) also in 2000, a study by Kurabayashi, et al. entitled *Eicosapentaenoic acid effect on hyperlipidemia in menopausal Japanese women* analyzed the effects of pure EPA in patients with high lipid and lipoprotein levels. The Kurabayashi Study found that pure EPA lowers triglycerides without increasing LDL-C but also has a "stimulatory effect on lipoprotein degradation" which resulted in significantly lower ApoB levels in patients who took EPA than the control group;

(c) in 2001, a study by Katayama et al. entitled *Efficacy and Safety of Ethyl Icosapentate (Epadel®) Given for a Long Term Against Hyperlipidemia* ("Katayama") likewise analyzed the effect of EPA on lipids over time. Katayama found that pure EPA lowered triglycerides without increasing cholesterol and did so without any impact to patients' safety; and

(d) in 2007, a paper by Yokoyama et al. entitled the *Japan EPA Lipid Intervention Study* (JELIS) analyzed the "effects of [EPA] on major coronary events in hypercholesterolaemic patients." The JELIS study concluded that "EPA treatment reduced the frequency of major coronary events."

36. Defendants were fully aware of Epadel and the studies demonstrating its various positive effects. In fact, prior to Vascepa approval in the U.S., Defendants cited these studies to convince investors that Vascepa would likewise demonstrate an ability to lower triglycerides without raising LDL-C. For example, in March 2010, Amarin cited Mori and Kurabayashi for the conclusion that "DHA Raises LDL-C" while "EPA is LDL Neutral."

37. In short, at the time of the Vascepa launch in 2013, the beneficial effects of EPA were well known to Defendants. The known benefits at the time included, among other things, lowering triglycerides, lipoproteins, ApoB, and cholesterol. It was also known (through the JELIS study) that patients who took pure EPA had a lower risk of cardiovascular events.

C. Exclusivity in the U.S.: NCE Protection vs. Patent Protection

38. In an effort to incentivize pharmaceutical innovation in the U.S., the federal government designed regulations that reward companies with new or innovative products by granting exclusive access to the U.S. market for a set period of time. The two primary forms of exclusivity for pharmaceutical products are patents issued by the USPTO and regulatory exclusivities granted by the FDA. Patents create intellectual property rights for the patent owner, which entitle it to sue entities that infringe upon those rights during the term of the patent. Regulatory exclusivities, by

contrast, are regulations that prevent competing companies from taking certain actions for a set period of time.

39. Market exclusivity is highly valuable to the owner of the drug that has exclusive access. During the period of exclusivity, the owners can charge higher prices and capture more market share than they could have otherwise. Also, longer periods of exclusivity are exponentially more valuable than shorter periods. This is because early years of exclusivity are often spent trying to create a market for the previously unknown drug. As the market develops and grows over time, the owner's ability to capitalize on exclusive access increases. Accordingly, the latter years of a patent are often much more valuable than the initial years.

D. The Fundamentals of Regulatory Exclusivity

40. The FDA regulates the marketing of pharmaceuticals in the interest of public health. In order to obtain approval for a new or "brand-name" drug from the FDA, a company must file a New Drug Application ("NDA") demonstrating that the drug's benefits outweigh its known and potential risks. In order to make this showing, a company typically presents data from clinical trials that make significant showings regarding the drug's efficacy and safety.

41. Generic drugs are exact copies of brand-name drugs, and when they enter the market they drive down drug prices and result in significant savings for the general public. In order to promote the development of more generic drugs and to speed up

the approval process, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act." Pub. L. No. 84-417, 98 Stat. 1585 (1984). Under the Hatch-Waxman Act, the owners of bioequivalent drugs only need to file a truncated ANDA, in which the applicant can rely upon the safety and efficacy data of the original manufacturer.

42. But the Hatch-Waxman Act places limitations on the timing of ANDA filings. These limitations vary depending on the specific characteristics of the precursor drug. Of particular importance here, the Hatch-Waxman Act provides five years of exclusivity to drugs that qualify as an NCE. The consideration is straightforward: A drug is judged to be an NCE if the FDA has not previously approved that drug's active ingredient. This prohibition holds even if the ANDAs are directed toward a different use of the active ingredient.[2]

43. As part of the ANDA process, the applicant must submit a certification regarding the patent protection of the original NDA drug, explaining why the proposed generic version will not infringe a viable patent. One option for meeting this requirement, codified in paragraph 4 of the regulation, is to submit a certification explaining the patent is "invalid, unenforceable, or will not be infringed by the

[2] NCE exclusivity acts as data exclusivity, meaning the ANDA filer is not entitled to rely on the clinical trial data of the NDA filer. It therefore does not preclude the FDA from accepting an application submitted by an entity that has performed its own preclinical and clinical studies.

manufacture, use, or sale of the drug product for which the abbreviated application is submitted" (a "Paragraph IV Certification"). CFR 314.94(a)(12)(i)(A)(4). ANDA applicants that submit a Paragraph IV Certification may file their ANDA one year early, or after four years of NCE exclusivity.

44. An applicant making a Paragraph IV Certification must notify the patent holder of its position, which then entitles the patent holder to bring a lawsuit for patent infringement against the ANDA applicant. If the patent holder files an infringement suit, the FDA automatically stays the ANDA approval for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. This 30-month stay gives the patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug.

E. The Fundamentals of Patents

45. The standard for patent protection is much higher than the standard for NCE exclusivity. The Patent Act of 1952 (the "Patent Act") requires innovators to prepare and submit applications to the USPTO if they wish to obtain patent protection. USPTO officials called "examiners" then assess whether the application merits the award of a patent. To be patentable, a drug must be useful, novel, and non-obvious. To satisfy the "useful" requirement, the drug must provide a tangible benefit. 35 U.S.C. §101. To be judged "novel," the invention must not be "in public use, on sale, or otherwise available to the public" before the patent application was filed. 35

U.S.C. §102. To be "non-obvious," the drug invention must be distinct enough from existing drugs that its invention would not be obvious to "a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. §103. This hypothetical person is colloquially referred to as the "POSA" or "POSITA."

46. When analyzing the obviousness of a pharmaceutical patent, the examiner must consider what the POSITA could derive from the "prior art." According to the USPTO, prior art comprises all "information known publicly before the effective filing date of a U.S. patent application," and is not limited by geography. Accordingly, prior art includes information contained in foreign patents and patent applications, journal articles, and scientific papers. The applicant carries a duty of disclosure that, among other things, requires it to disclose any known prior art that is material to the patentability of the product.

47. When assessing obviousness, examiners specifically consider: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; and (3) the level of ordinary skill in the pertinent art. In addition, examiners assess certain "secondary considerations," or "objective indicia" of non-obviousness already demonstrated by the product, such as long-felt but unsolved need, commercial success, skepticism from skilled artisans, or unexpected results created by the claimed invention. The crucial secondary consideration in this case is "unexpected results created by the claimed invention." To establish this objective

indicia of non-obviousness, the patent applicant must demonstrate that the drug provides some benefit to patients that was not known or expected from the prior art.

48. As part of the patent application process, the owner of the patent interacts with the patent examiner through formal writings filed with the USPTO. After the patent application is received, the examiner issues office actions that identify deficiencies in the application, which the owner can attempt to rectify by either amending the patent application, submitting argument in support of the existing application, or both. Ultimately, the examiner will either approve the application by issuing a Notice of Allowance or reject the application by issuing a Final Rejection.

49. Pursuant to 37 CFR §1.56 ("Rule 56"), all individuals associated with the filing and prosecution of a patent application carry a duty of candor and good faith in dealing with the USPTO. Rule 56 concerns every person who is "substantively involved in the preparation or prosecution of the application" and this duty of candor includes a duty to disclose to the USPTO "all information known to that individual to be material to patentability" of the drug. Applicants violate Rule 56 when they engage in "inequitable conduct," or intentionally mislead the USPTO about material information. One form of inequitable conduct is to "bury" highly material prior art in a long list of other references in an effort to conceal the piece of material prior art from the examiner. An applicant that engages in inequitable conduct subjects itself to harsh consequences, including invalidation of the patent.

50. While patentability requires a more significant showing than the showing necessary for NCE exclusivity, the reward for meeting that higher standard is also more significant. If issued, the term of the patent is ordinarily set at 20 years from the date the patent application was filed. After issuance, the patent owner bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent owners who wish to compel others to observe their intellectual property may commence litigation in the federal district courts. The U.S. Court of Appeals for the Federal Circuit possesses exclusive national jurisdiction over all patent appeals from the district courts, while the U.S. Supreme Court possesses discretionary authority to review cases decided by the Federal Circuit.

F. Amarin Secures NCE Protection for Vascepa

51. Although Amarin was not the first company to develop EPA as a pharmaceutical product, it was the first Company to gain approval from the FDA to sell the product in the United States. In late 2009, Amarin launched a clinical trial entitled *Efficacy and Safety of AMR101 (Ethyl Icosapentate) in Patients With Fasting Triglyceride (Tg) Levels ≥ 500 and ≤ 2000 mg/dL* ("MARINE") to demonstrate that patients with severe hypertriglyceridemia taking Vascepa had a meaningful reduction in triglycerides relative to patients taking a placebo. At the time of the MARINE trial, studies in Japan (such as Katayama) had already established that pure EPA would achieve this result. The MARINE study concluded in July 2011, and confirmed the

prior studies showing that EPA resulted in a statistically significant reduction in triglycerides.

52. Amarin submitted the MARINE data to the FDA and, on July 26, 2012, the FDA approved Vascepa for treatment of patients with severe hypertriglyceridemia. Amarin also received NCE exclusivity starting on the day of FDA approval, July 26, 2012, with its five-year term set to expire on July 26, 2017. Pursuant to the Hatch-Waxman Act, ANDA filers that submit a Paragraph IV Certification challenging the validity of the Vascepa patent could file one year earlier, on July 26, 2016.

G. Defendants Withhold Material Information from the Examiner and Secure Patent for Vascepa

53. On February 9, 2010, Amarin submitted a patent application to the USPTO regarding Vascepa titled "Methods of Treating Hypertriglyceridemia." The crux of the patent claims covered an invention that consisted of treating patients diagnosed with triglyceride levels between 500 and 1,500 mg/dl with 4 grams of 96% purified EPA over a 12-week period. The claimed outcomes of the EPA treatment program included, among other things, a reduction in triglycerides and ApoB without raising LDL-C levels.

54. As part of any patent application, the applicant files a Form PTO-1449 ("Form 1449") which identifies prior art known to the applicant to be material to the patentability of the claims in the application. An applicant's completion of Form 1449 must be consistent with Rule 56's duty of candor and good faith, which requires the

applicant to identify all known material prior art that is relevant to the patent application.

55. On May 23, 2011, Amarin submitted to the PTO its first Form 1449, which included 29 previously published studies and/or papers as well as 6 previously issued U.S. patents, but did not mention the Kurabayashi Study. Then, on June 3, 2011, Amarin submitted an additional Form 1449. That Form 1449 included ***more than 300 references*** to prior art studies and papers, and over 50 previously issued U.S. and foreign patents. The Kurabayashi Study was buried among these references, but was never discussed in the interactions that followed between Amarin and the patent examiner.

56. On June 20, 2011, the patent examiner rejected the claims of the patent application for the first time (on a non-final basis) in large part because he found, based on the prior art, that it was obvious EPA administration would lead to a reduction in triglycerides without a resulting increase in LDL-C levels. In the office action correspondence that was submitted along with the first rejection, the patent examiner noted:

> [T]he percentage of change in TG [triglycerides], HDL, LDL, Lp-PLA2, APO B, etc. will natfurally flow from the teachings of (or made obvious by) the prior art (Katayama) since the same population (individuals with high TG and high TC) are being treated with the same medication (EPA-E) and same or similar amounts and for same or similar periods of time.

57. On June 23, 2011, Amarin filed a response which focused heavily on attempting to distinguish the prior art cited in the patent examiner's initial rejection from the claimed invention. Amarin argued: (1) it is not *prima facie* obvious from the prior art that administration of EPA would produce no corresponding increase in LDL-C because the prior art used a different patient population from the claimed invention; and (2) even if it is *prima facie* obvious from the prior art that LDL-C levels will not increase with administration of EPA, Amarin's MARINE trial produced unexpected results – that is, LDL-C levels did not statistically increase with administration of EPA. Amarin did not argue that a reduction in ApoB levels was an unexpected result.

58. On August 18, 2011, the patent examiner issued another office action. This time, the office action was styled as a final rejection of all proposed claims. The patent examiner reiterated his findings from the first rejection that no increase in LDL-C flows naturally from the prior art. Once again, there was no discussion at all regarding the effects of EPA on ApoB levels or the Kurabayashi Study.

59. Amarin could respond to this final rejection in one of three ways: (1) do nothing, in which case the rejection would stand; (2) appeal to the Patent Trial and Appeal Board; or (3) request continued examination, which would allow Amarin to continue its correspondence with the patent examiner.

60. On September 21, 2011, Amarin submitted a Request for Continued Examination ("RCE") pursuant to 37 C.F.R. §1.114. Along with the RCE, Amarin submitted remarks in reply to the patent examiner's final rejection of the claims. It also submitted a declaration from Dr. Howard Weintraub, a cardiologist, in an attempt to add weight to their previously argued remarks that no increase in LDL-C is an unexpected result of the administration of Vascepa. Amarin argued:

> According to Dr. Weintraub . . . Lovaza and Epadel had a very similar impact on both TGs and LDL in the subjects with borderline high/high TGs. As a result, Applicants submit that a person of ordinary skill in the art (as of the priority date of the instant application) reading these references, if anything, would have expected a drug containing > 96% EPA, such as [Vascepa] or Epadel after 2005), to produce an outcome similar to that of Lovaza as a monotherapy in subjects with very high triglycerides, namely a significant increase in LDL. Contrary to that expectation, [Vascepa] significantly reduced TGs in subjects with very high triglycerides without increasing LDL to a statistically significant level.

61. On November 4, 2011, the patent examiner rejected the claims for a third time. The patent examiner was not persuaded by Amarin's arguments or Dr. Weintraub's analysis, stating:

> [T]he fact that ethyl-EPA has shown to have almost no effect on the LDL cholesterol levels on the patient population with triglycerides above 500 mg/dl, it cannot be considered "unexpected" because: 1- the population with less than 500 mg/dl of triglycerides also showed almost no effect in the LDL levels when treated with ethyl-EPA (see above Table 1 presented by Applicant and see Katayama reference in above rejection), as such ***from these teachings it will not be unexpected for ethyl-EPA not to have a major impact on the levels of LDL cholesterol on patients with very high TGs***. 2- The fact that Lovaza (a mixture of ethyl-EPA, DHA and other omega 3 fatty acids) showed a similar

> behavior to EPADEL ® (highly purified ethyl-EPA) in the borderline high/high TG population (150 to 500 mg/dl) with no effect on LDL levels, and then a noticeable increase in LDL in the very high TG population, cannot be considered predictive of how a pure omega-3-fatty acid like ethyl-EPA will behave under similar circumstances. ***The fact that the prior art (Okumura and Katayama) teach that Epadel ® (a highly purified ethyl-EPA) does not have a major effect on the LDL levels of individuals with less than 500 mg/dl of triglycerides seems to be more indicative of how the administration of ethyl-EPA will affect the LDL levels than the administration of a mixture of omega-3-fatty acids (Lovaza) to individuals with triglycerides above 500 mg/dl***.

62. Throughout all of its replies up to this point, Amarin focused almost exclusively on arguing that a reduction in triglyceride levels along with a decrease or no increase in LDL-C levels was not *prima facie* obvious in light of the prior art; or in the alternative, that it was an unexpected result of the administration of Vascepa.

63. On January 13, 2012, Amarin submitted its reply to the patent examiner's third rejection, and dramatically changed its strategy. In a last-ditch effort to get its patent approved, Amarin now argued that the reduction in ***ApoB*** – not LDL-C – was unexpected and merited patent protection for Vascepa.

64. Specifically, in its reply, Amarin stated: "The claimed reduction in [ApoB] is unexpected in view of the prior art of record as set forth in Table A," and included the following table:

Table A. Summary of apoB Outcomes with Lovaza, Epadel, Grimsgaard Composition and AMR101

Mean Baseline TG	Lovaza/Omacor 4 g per day	Epadel (Okumura) 1.8 g per day	95% E-EPA (Grimsgaard) 4 g per day	AMR101 4g per day
	Comparative Results			Applicant's Results (Not Prior Art)
< 150 mg/dl (normal lipids)	--	--	No statistically significant differences among all groups[1]	
150 - 499 mg/dl	7% increase[2] or no statistically significant change vs. control[3]	No statistically significant change from baseline[4]	--	ANCHOR Trial[5]
> 499 mg/dl	No statistically significant change vs. control[6]	--	--	MARINE Trial 8.5% decrease vs. control highly significant (p=0.0019)

65. Inexplicably, Amarin completely failed to mention the Kurabayashi Study anywhere in its argument or in Table A. The Kurabayashi Study, which Defendants knew about because they had previously used it to promote the attributes of Vascepa, found that the administration of purified EPA resulted in a reduction of triglycerides as well as a ***statistically significant reduction in ApoB levels of 6.9%***. In other words, the omitted Kurabayashi Study demonstrated the exact outcome that Amarin claimed was unexpected.

66. To support its misleading assertions, Amarin produced an expert declaration by Dr. Harold Bays, an endocrinologist. Amarin relied on Dr. Bays' expert declaration as further support for its argument that a reduction in ApoB from

administration of purified EPA was unexpected and not contained in the prior art. Amarin claimed:

> Applicant previously made of record (See Bays Declaration I) evidence that in the MARINE trial, 4 g per day of [Vascepa] reduced apoB and that the reduction was statistically significant compared to control. Both Katayama and Saito are completely silent as to apoB and contain no teaching regarding a reduction in apoB. As such, ***there is no evidence of a reasonable expectation of success or any predictability with respect a reduction in apoB***. In fact, as is discussed below, ***the successful reduction of apoB compared to a control group was entirely unexpected***. See Bays Declaration II at 15.

Once again, Amarin misled the patent examiner by omitting any reference to the Kurabayashi Study.

67. On March 2, 2012, the patent examiner rejected the claims for a ***fourth*** time. Because Amarin's claims still focused in part on Vascepa's reduction in triglycerides, the patent examiner noted that "there is a reasonable expectation of success that the administration of 4 g of 96% pure EPA-E to individuals with TG levels equal or above 500 mg/dl will also result in the decrease of TG levels (***regardless of their effect on Apo-B levels*** or other biological markers)."

68. On May 16, 2012, Amarin submitted its fourth and final response to the patent examiner. In the response, Amarin shifted its focus even further toward its claim that a reduction in ApoB was an unexpected result of the administration of Vascepa. Amarin submitted the following chart showing a summary of studies

intended to support Amarin's conclusion that a reduction in ApoB was not supported by the prior art:

Table 1. Evidence Supporting No Expectation of apoB Reduction as Claimed

Paper	Baseline TG levels	Intervention	LDL-C Outcome	ApoB Outcome
Katayama	TG 279.9 mg/dl	2.7 g Epadel for up to 24 months	Not reported	Not reported
Grimsgaard	TG: 107 mg/dl	4 g 95% E-EPA with 1.2% E-DHA for 8 weeks	NS difference from corn oil or DHA group	NS difference from corn oil or DHA group
Okumura	TG: 274 mg/dl	1.8 g Epadel per day for 3 months	NS difference from baseline	NS difference from baseline

Hayashi	TG: 300 mg/dl	1.8 g E-EPA for 8 weeks	NS difference compared to baseline	NS difference compared to baseline
Mori	TG:176 mg/dl	4 g 96% E-EPA, 92% E-DHA or olive oil for 6 weeks	E-EPA group: NS difference	Not reported
Park	TG <200 mg/dl	EPA and DHA	NS difference compared to olive or safflower oil	No reduction during fasting measurements after 4 weeks of EPA administration
Connor	TG ~ 1432 mg/dl	Control, Fish oil or vegetable oil	Significant **increase** in LDL-C in the fish oil group versus both control and vegetable oil	Decrease
Matsuzowa 1991	TG: 331 mg/dl	2.7 g Epadel	NS difference from baseline at 12 weeks	NS difference from baseline at 12 weeks
Lovaza Approval Studies	TG: 250 – 850 mg/dl See p. 4 of Lovaza Approval Package for overview of various studies	4 g EPA and DHA	Increased	NS difference in any of the reported studies compared to placebo
Hasayaka 1995	TG: 114.6 mg/dl	1.8 g Epadel	NS difference	Not measured
Aoki 1991	TG: 132 mg/dl	1.8 g Epadel	NS difference	Significant Increase

NS = Not statistically significant

69. Amarin provided the following explanation of the above chart from Dr. Bays:

> Neither Connor nor Park had study designs such that a person trained in endocrinology and lipid disorders would consider them predictive of the effects of E-EPA 4 grams per day (such as [Vascepa]) on fasting apoB levels in human subjects with TG ~500mg/dl.
>
> All the other studies listed either did not measure, or did not support a reduction in apoB levels.
>
> To summarize my prior two Declarations, one of the unexpected findings of the MARINE trial was the significant reduction in apolipoprotein B ("apoB"). ***Prior to the MARINE trial, I am aware of no directly applicable published clinical trial data supporting highly pure ethyl eicosapentaenoate ("E-EPA") as reducing ApoB in patients with TG levels ~500 mg/dl. Thus, a person trained in endocrinology and lipid disorders would not have expected that 4 g per day of [Vascepa] (as studied in the MARINE trial) would have reduced apoB to a statistically significant degree compared to a placebo control group.***

70. Amarin's and Dr. Bays' assertions were false or misleading, and violated the Company's duty of candor with the patent examiner. Instead of providing the patent examiner with a true and accurate picture of the prior art, Amarin again inexplicably left out the Kurabayashi Study. In fact, Amarin never mentioned the crucial study anywhere in its years-long correspondence with the examiner. The only reference in the file to the Kurabayashi Study is on the Form 1449, where it is buried among ***over 300 other prior art references***.

71. On September 6, 2012, the patent examiner published a Notice of Allowance, officially granting Amarin a patent covering Vascepa. In the Notice of

Allowance, the patent examiner maintained that the claims in the patent were *prima facie* obvious based on the prior art. However, without the benefit of the Kurabayashi Study, the examiner believed Amarin's argument that a reduction in ApoB from treatment with purified EPA was an unexpected result. Based on this secondary consideration, he granted the patent. In his decision, the patent examiner parroted the misrepresentation from Amarin:

> ***The prior art is either silent or teaches that there is no statistically significant change in Apo-B levels when patients with TG levels less than 150 mg/dl or between 150-499 mg/dl are treated with either 96% pure ethyl-EPA*** or a mixture of ethyl-EPA and DHA, or when a mixture of ethyl-EPA and DHA was administered to patients with TG levels above 500 mg/dl (see item 25 on page 6 and Table 1 of the Bays' declaration dated 05/16/2012; *see also* Table A on page 15 of Applicant's response dated 01/13/2012). ***Applicant also presented convincing arguments (see Bays' declaration dated 05/16/2012, items 10 through 24 on pages 2 through 6) against the three references presented by the Examiner (Connor et. al., Fisher et. al. and Park et. al.) regarding the predictability of lowering Apo-B with 96% pure ethyl EPA in patients with TG levels above 500 mg/dl***.

72. Amarin's subsequent patent applications for Vascepa were continuations of this favorable issuance, and were subject to much less rigorous review. The patent examiner responsible for reviewing the continuation applications later issued materially identical statements of allowance.

H. Amarin's Competitors Immediately Challenge its Patents

73. On July 26, 2016, the first day permissible under the regulatory exclusivity rules, three different generic manufacturers – Hikma Pharmaceuticals PLC

("Hikma"), Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"), and Teva Pharmaceuticals USA, Inc. ("Teva") – filed ANDAs for generic versions of Vascepa. Each ANDA filer also submitted a Paragraph IV Certification asserting the Vascepa patent was "invalid, unenforceable, or would not be infringed" by the sale of an exact replica.

74. Shortly thereafter, on October 31, 2016, Amarin filed its first patent infringement suit against Hikma in the District of Nevada, immediately followed by suits filed against Dr. Reddy's on November 4, 2016, and against Teva on November 18, 2016, all alleging the ANDA filings had violated several patents pertaining to Vascepa. Teva ultimately settled its litigation with Amarin in May 2018, but Hikma and Dr. Reddy's maintained the dispute throughout the course of the litigation and subsequent appeals (the suits were consolidated on November 7, 2017).

75. In those proceedings, the remaining ANDA filers, Hikma and Dr. Reddy's, made counter claims arguing the Vascepa patents were invalid because Vascepa was an obvious innovation from the prior art, citing the studies of Epadel in Japan. They further argued that secondary considerations, such as addressing unmet needs or achieving unexpected results, did not overcome the *prima facie* finding of obviousness, because Vascepa did neither. Specifically, with regard to the "unexpected result" that Vascepa lowered ApoB levels, the ANDA filers argued the examiner had "overlooked (and [Amarin] did not point out) prior art that expressly showed this result." In particular, ANDA filers Hikma and Reddy's argued that

"Kurabayashi showed that patients treated with 96.5% purified EPA for 48 weeks experienced a reduction in Apo B by 6.9%," which was "highly statistically significant."

76. The ANDA Litigation proceeded all the way to a bench trial before Chief Judge Miranda M. Du. Ultimately, on March 30, 2020, Judge Du ruled that the patents were "invalid as obvious." Specifically, she found the patents were "*prima facie* obvious" based on the prior art, noting that even the USPTO examiner who issued the patents had "maintained its finding from earlier rejections that the prior art rendered all of the claims *prima facie* obvious." The Court further found Amarin's claimed "unexpected benefits" were not unexpected, but rather "predicted by the relevant prior art." Specifically, Judge Du correctly noted, although "Kurabayashi suggested that EPA reduced Apo B levels," the "examiner did not consider Kurabayashi" because it "did not have all material facts before it." Judge Du concluded that, without this secondary consideration, Amarin had only "weak evidence" in support of the other secondary considerations that alone could "not overcome the Court's finding that all Asserted Claims are *prima facie* obvious."

I. Amarin Significantly Expands Label to Include Treatment for Cardiovascular Issues

77. In November 2011, prior to Vascepa's launch in the U.S., Amarin initiated an additional clinical outcomes trial called REDUCE-IT to demonstrate that Vascepa reduced the likelihood of cardiovascular events in patients with elevated

triglycerides. The REDUCE-IT trial focused on patients who were already taking a statin to lower cholesterol, and then compared patients who added either Vascepa or a placebo. Researchers then followed the patients for several years to track which group suffered more cardiovascular events, on a statistically significant basis.

78. According to Amarin, if the REDUCE-IT trial succeeded in showing that Vascepa lowered cardiovascular risk, then the use and profitability of Vascepa would exponentially increase. According to Thero, positive REDUCE-IT results would mean that a daily dose of Vascepa would be appropriate treatment for everyone with elevated triglycerides, which comprises "roughly 1 in 4 adults in the United States."

79. At the time they launched the REDUCE-IT trial, Defendants knew the JELIS study in Japan had already proven that "EPA treatment reduced the frequency of major coronary events." Indeed, as the REDUCE-IT trial was underway, Amarin executives acknowledged it closely mirrored the JELIS study, and therefore expected the same success. For example, in August 2018, before the REDUCE-IT results were released, Amarin's then Chief Medical Officer Craig Granowitz told investors "we believe that REDUCE-IT has a very high probability of success" because "JELIS was the most similar to REDUCE-IT in terms of the drug, a pure EPA product as well as the dosing."

80. On September 24, 2018, Amarin announced the REDUCE-IT study had met its primary endpoint. Consistent with the results in the JELIS study, REDUCE-IT

demonstrated that patients taking purified EPA were at substantially less risk for a cardiovascular event than patients taking a placebo.

J. Defendants Drive Up the Price of Amarin's ADSs and Then Immediately Sell Their Shares

1. Defendants Condition the Market to React Positively to REDUCE-IT Study Results

81. The Class Period begins on September 24, 2018 – the day Amarin announced the positive REDUCE-IT results. At the time, Defendants knew or recklessly disregarded two crucial pieces of material information investors did not know or understand. First, Amarin knew or recklessly disregarded that the Vascepa patents were issued in error, and that the pending ANDA Litigation would soon expose that error and invalidate the patents. Amarin had only secured the patents because the examiner incorrectly concluded that a decrease ApoB was an "unexpected result" of Vascepa. In reality, the examiner did not consider the Kurabayashi Study, which had unequivocally demonstrated years prior that pure EPA lowers ApoB to a statistically significant degree. Defendants understood Amarin's patents would eventually be invalidated by the ongoing ANDA Litigation.

82. Second, Defendants knew or recklessly disregarded that investors had an inflated impression of Vascepa's prospects after REDUCE-IT. Investors thought Vascepa had sole access to a market comprised of "roughly 1 in 4 adults," each of whom would take the product daily. In other words, if Vascepa could realize this

potential, ***it would be a blockbuster, billion-dollar drug several times over, and one of the most ubiquitous pharmaceutical products of all time***. Investors could not and did not appreciate that, in fact, Amarin was not entitled to be the sole proprietor of purified EPA. Instead, the Company would have to compete with upcoming generic products, which would drive down Vascepa's price, market share, and profitability.

83. As a result, Defendants understood they were in a brief window where Amarin's share price was heavily inflated until the Vascepa patents were invalidated. Rather than share the realities of Vascepa's prospects with investors, Defendants schemed to inflate the price of the Company's ADSs as high as possible and then capitalize on the high price for personal gain.

84. Even before Defendants announced the REDUCE-IT results, they conditioned the market to believe positive results would be transformational for the Company. For example, in January 2018, Thero stated: "We see ourselves expanding to a multibillion dollar opportunity with clearly a differentiated product" because Defendants expected that Vascepa would treat "multiple millions of patients . . . if we get the kind of results that we're working towards in our REDUCE-IT outcomes study."

85. Investors bought Defendants' story. For example, analysts for Cantor Fitzgerald issued a report on January 23, 2018 which stated:

> [A] potential positive read-out from the REDUCE-IT outcomes study, expected in mid-2018, may not only expand the indicated patient

> population of ~4M to ~75M, but also, for the first time, may have an outcomes study that draws a straight line between triglyceride levels and cardiovascular risk, possibly changing how cardiovascular risk is managed and treated and potentially creating a multi-billion-dollar market opportunity.

Similarly, a January 23, 2018 analyst report from Jefferies noted that the "time is drawing closer to transformative REDUCE-IT data," with the Jefferies analysts "remain[ing] optimistic for a positive outcome and see Vascepa as a multi-$B blockbuster." Then, on February 23, 2018, analysts for SunTrust Robinson Humphrey issued a report which stated: "REDUCE-IT read-out in 3Q18 is the most important catalyst," and if REDUCE-IT meets the primary endpoints, "we expect physicians to view this as clinically meaningful, potentially increasing Vascepa's commercial potential to >$1B in annual sales." And an August 2, 2018 analyst report from H.C. Wainwright & Co proclaimed: "Vascepa may become the standard of care following REDUCE-IT outcome."

2. Positive REDUCE-IT Results Cause Dramatic Price Increase in Amarin ADSs

86. By the time the REDUCE-IT results were finalized and published, Defendants had conditioned investors to believe that positive results meant Vascepa would become a multi-billion dollar drug. When Amarin announced positive results on September 24, 2018, the corresponding share price movement was instant and dramatic. On the prior trading day, September 21, 2018, the share price closed at $2.99 per share with a trading volume of 4,265,400. On the day the results were

announced the share price soared to $12.40 per share on a trading volume of 163,103,800, increases of 415% and 3,824%, respectively.

87. Market analysts made clear that the soaring optimism came from the REDUCE-IT results and investors' belief about what those results meant for Vascepa's prospects. For example:

(a) Cantor Fitzgerald reported the same day that due to the REDUCE-IT results: "Peak sales could be meaningfully higher than $1B. REDUCE-IT results today could change the treatment paradigm for CV disease. There are 57MM-70MM patients with elevated triglycerides (TG) to the level that AMRN looked at in its study." The report further stated: "There is no other drug like Vascepa out there today" and "[t]he effects of Vascepa are broad."

(b) On the same day, Jefferies also reported: "Shares rose 300%+ after AMRN announced unprecedented CV benefit for its landmark CVOT trial (REDUCE-IT). We think the 25% MACE reduction clearly gives AMRN an opportunity to grow sales to $2-3B."

(c) The following day, H.C. Wainwright & Co reported: "With REDUCE-IT data in hand, Amarin now holds an ace card." The report further stated: "Amarin now has 'blue sky' potential, and all roads should be clear and lead to Rome" and that "[w]ith REDUCEIT data in hand, we view Amarin's market positioning as greatly strengthened."

3. Defendants and Other Top Executives Immediately Capitalize on the Inflated Share Price, Dumping Millions of Dollars' Worth of Their Personal Shares on the Day the Results Became Public

88. Rather than hold on to their shares to await for the bright future they had painted for investors, Defendants did the opposite and sold large portions of their holdings. Take, for example, Kennedy, the General Counsel of Amarin who admitted he had "[l]ed Amarin's strategy in the successful prosecution of over 40 patents," and therefore had a clear sense of the patents' vulnerabilities. Kennedy did not act like someone who believed Amarin would treat a quarter of Americans for the upcoming decade. Instead, on the day the REDUCE-IT results were announced, Kennedy sold ***1,079,706 shares for $11,397,855***. Kalb, the CFO, also spent the day unloading shares, selling ***150,000 shares for $1,562,514***.

89. Other top executives also sold sizeable chunks of shares shortly after the REDUCE-IT news was announced. Joseph Zakrzewski, a director and CEO during the Vascepa patent prosecution, sold $5,298,767 worth of his shares on the day of the announcement. Steven Ketchum, the President of Research and Development and Chief Scientific Officer, sold $14,865,673 worth of shares in the week following the announcement.

4. Defendants Maintain Inflation in Amarin ADSs with Further False Statements While Amarin Executives Continue to Sell Their Own Shares.

90. After the REDUCE-IT results became public, but before Amarin lost its patents, Defendants continued to stress to the market that Vascepa would serve millions of patients, bring in billions of dollars in revenue, and completely transform the Company. For example, Thero stated: "we can help millions of patients with this drug," "we're going to grow Vascepa into a multiple-billion-dollar opportunity," and that Vascepa would "lead a new paradigm in patient care."

91. Accordingly, investors continued to react favorably to Defendants. For example, a November 12, 2018 analyst report by H.C. Wainwright & Co. stated that "the REDUCE-IT trial data may be viewed as 'unprecedented' and 'paradigm-changing' in the context of minimal or modest benefits historically achieved by various therapies on top of statins." On January 17, 2019, H.C. Wainwright & Co. would further report: "management believes that Vascepa has a strong long-term prospect that would grow over the next 8-10 years, and harbors great confidence in Vascepa to achieve billions in sales." Jefferies analysts issued a report on January 7, 2020 stating:

> This remains one of the strongest launch drugs we've seen in the biotech industry and hence we think 2020 sales will also look good. Indeed, the company has generally met or exceeded consensus in each of the last 5+ quarters and has continually raised guidance. We have confidence in our $3B+ peak estimate and believe the stock remains generally undervalued at its current $21 stock price, or $8.8B fully

> diluted, implying only around 3x peak sales. We think it's worth more around $12B or 4x peak sales or another 25%+ upside from here.

92. Defendants also specifically addressed the ongoing ANDA Litigation and told investors not to worry about the outcome. For example, Thero stated: "Any good product gets ANDA filers. It'd be almost insulting if they weren't." Thero also assured investors that the litigation was trending "almost entirely in our favor." In fact, Defendants stressed they could expect the patents to grant Vascepa exclusive rights to sell purified EPA in the U.S. until 2030, telling investors: "We have now over 100 patents internationally, predominantly in the United States, most with expiries in 2030" and that "[w]e have global rights to the product, and we feel like we're just getting started."

93. Again, investors bought in. For example, a September 25, 2018 analyst report by Cantor Fitzgerald was titled "Solid IP Will Keep Vascepa Safe From Competition For A Long Time." The report noted:

> Given peak sales potential of billions of dollars, one common question we have received from investors is around the company's IP strength. (*i.e.*, What is stopping other companies from launching a generic version of Vascepa?) After speaking with AMRN and reviewing the public record of its patents and ANDA-related matters on the USPTO website, we believe AMRN has solid IP.

94. The report further stated that "Vascepa's IP will keep out generics until August 2029+." Similarly, an October 4, 2018 Cantor Fitzgerald analysts report stated: "Concerns about mineral oil, IP and OTC use are overdone. . . . We think

AMRN's IP is strong and its settlement with TEVA (Neutral) through August of 2029 underscores this."

95. Meanwhile, Defendants continued their massive selloff, with Kennedy leading the way. Although he had convinced investors that "our patents go out to 2030" and that the patent litigation so far had gone "very favorably for us," he continued to dump his personal shares and accumulate unimaginable wealth. From the time the REDUCE-IT results were announced until the time the patents were invalidated, ***Kennedy sold 89.19% of his shares for $36,504,087***. This stands in stark contrast to his trades in the two years leading up to the Class Period, in which Kennedy sold only approximately $2 million worth of Amarin ADSs.

96. The other Individual Defendants also sold large portions of their holdings in suspicious ways. Kalb dumped 65% of his shares between the date Amarin announced the REDUCE-IT results and the date Vascepa's patents were invalidated, amassing $9,779,380 in personal gains. He did not sell any shares in the two years leading up to the Class Period.

97. Thero sold 24% of his shares over the course of the Class Period for $36,790,688. Like Kalb, he had not sold any shares in the two years leading up to the Class Period. In fact, in the nearly nine years he had been Amarin's President before the Class Period, he had made only one sale of shares, in April 2012, for a total of $1,503,223.

98. Over the course of the Class Period, the three Individual Defendants netted $83,074,154 for themselves. Seven other insiders – Joseph Zakrzewski, Steven Ketchum, Chief Commercial Officer Aaron Berg, and Directors Lars Ekman, Kristein Peterson, David Stack, and Jan Van Heek – also engaged in the massive sell off of Amarin ADSs. In total, the 10 executives extracted $162,979,042 from the market for their personal gain over the course of the Class Period. This amount is astonishing by any measure, but the results are particularly notable when compared to the modest market capitalization of this single-product Company. The day after the Class Period, after the inflation in the price of Amarin ADSs had dissipated, the market capitalization of Amarin was just over $2 billion.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS

A. False and Misleading Statements Relating to Vascepa's "Unique" Characteristics

99. On January 11, 2018, Thero participated in the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

> ***We think that Vascepa is unique in that it can lower triglycerides without raising LDL. And as you'll see from our clinical data, it has a placebo-like safety profile***.
>
> * * *
>
> And that sort of brings me back to sort of a recap, which is that we are addressing multiple, very large markets. We're growing in a market that we're addressing today, which is important but niche market with our outcomes study. ***We see ourselves expanding to a multibillion dollar opportunity with clearly a differentiated product with a broad spectrum of lipid benefit and benefit in the atherosclerotic pathway.***

> ***Importantly, we don't increase LDL whereas earlier agents did***. We've had 2 successful Phase III studies. We've been growing revenues. We have strong managed care coverage. We have a strong team behind what we're doing, and we're very optimistic about our future.

100. On September 24, 2018, Amarin held a special call to announce the topline results of the REDUCE-IT study. Thero participated in the call and made the following materially false and misleading statements:

> ***An additional 25% relative risk reduction in REDUCE-IT, on top of well-controlled LDL cholesterol through statin therapy, positions Vascepa as the single most significant advance in preventative cardiovascular drug therapy since the advent of statin therapy. That's a big statement***. Let's pressure test that statement now.

101. On November 1, 2018, Thero hosted Amarin's 3Q 2018 earnings call and made the following materially false and misleading statements:[3]

> ***Publications in recent years have shown that the clinical effects of the active ingredient in Vascepa are unique.*** In addition to improving levels of various lipid and lipoprotein biomarkers, data suggest that this active ingredient may have beneficial effect on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation, cytokines, plaque formation, progression, platelet aggregation, thrombus formation and plaque rupture, all independent of triglyceride modification. ***We continue to reinforce that REDUCE-IT results are unique to Vascepa*** it cannot be generalized any prior generation add-on to statin, such as fenofibrates and that the REDUCE-IT results cannot be generalized to common fish oil or omega-3 mixture products, particularly those that contain the omega-3 acid, DHA.

* * *

[3] As used herein, "Q" means the Company's fiscal quarter, thus 3Q 2018 means Amarin's third fiscal quarter of 2018.

> And we are hoping that the scientific differentiation becomes clear because for patients who have serious medical conditions, we wouldn't would want them to be fooled by thinking that just the food alone is going to be sufficient to address their medical conditions. ***This is a – with the REDUCE-IT results an opportunity to provide medical therapy that is a new paradigm in treatment***, that should really be thought of as very different than the market that dietary supplements are going after and if dietary supplements try to crossover we'll take all actions appropriate both educate and thwart those efforts.

102. On November 13, 2018, Amarin filed a Form 8-K with the SEC, signed by Thero, and made the following materially false and misleading statements:

> The active pharmaceutical ingredient in Vascepa has a unique molecular structure. ***Vascepa has demonstrated clinical effects that have not been shown for any other product. The clinical effects of Vascepa demonstrated in REDUCE-IT cannot be generalized to any other product***.

103. On December 5, 2018, Thero participated in the Citi Global Healthcare Conference and made the following materially false and misleading statements:

> [Joel Lawrence Beatty, Analyst, Citigroup:] So with the successful REDUCE-IT results, Vascepa has succeeded where other triglyceride-lowering drugs have failed, including Lovaza and fenofibrates, some CETP inhibitors and niacin. Could you tell us about maybe what reason – what's the mechanism of action behind Vascepa succeeding where others have failed?
>
> [Thero:] ***Vascepa is unique not only in terms of its lipid effects, it lowers triglycerides significantly without raising your LDL cholesterol, but the effects of the drug go well beyond lipid management***. So if you look, for example, in each of the 8 key steps in the atherosclerotic process, beginning with endothelial cell function through inflammation, through thrombus and plaque stabilization, plaque reduction. There's data out there showing that EPA, the eicosapentaenoic acid, the active ingredient in our drug, has a positive effect on each of those steps as well as being a strong antioxidant and antiplatelet, anticoagulant.

104. On February 27, 2019, Thero hosted Amarin's 4Q 2018 earnings call and made the following materially false and misleading statements:

> ***We do not envision that we will compete with therapies for managing LDL cholesterol. Rather, Vascepa presents a new opportunity for healthcare professionals to help patients reduce their cardiovascular risk***.
>
> In the United States, approximately 1 in 4 patients have elevated triglycerides, a cardiovascular risk factor independent of LDL cholesterol or bad cholesterol, including more than 12 million patients in the United States on statin therapy. It is difficult for us to not be enthusiastic when presented with such an opportunity to improve patient care.

105. On May 1, 2019, Thero hosted Amarin's 1Q 2019 earnings call and made the following materially false and misleading statements:

> ***As a reminder, Vascepa capsules are not an omega-3 mixture but a drug product consisting of icosapent ethyl, the single active ingredient of which has been shown to have clinical effects which are different from any other drug***. Amarin remains at the forefront of the complex science of the varied effects of different omega-3 molecules in the application of such differences to cardiovascular risk reduction.

106. On September 4, 2019, Thero participated in the Citi Biotech Conference and made the following materially false and misleading statements:

> [Joel Lawrence Beatty, Analyst, Citigroup:] So assuming that Vascepa is approved for cardiovascular risk reduction indication, how does the Amarin prevent dietary supplement companies from claiming that their products have the same effect on patient health?
>
> * * *
>
> [Thero:] ***Vascepa is – has a mechanism of action, which is unique. The FDA has deemed it to be a new chemical entity. It works – again, on our website, a couple of dozen papers on the mechanism of action***

> ***for Vascepa and how it's different than other omega-3s, and we'll be looking forward to educate people on that science. And particularly, differentiation that exist through cardiovascular outcome studies where we have succeeded, and they failed.***

107. On December 16, 2019, Amarin hosted a special call. Craig Granowitz, Amarin's then Chief Medical Officer participated on the call and made the following materially false and misleading statements:

> ***I'm hearing tremendous support for Vascepa from the medical community that is familiar with this important drug. They emphasize, as do the medical society, that the results of REDUCE-IT should not be generalized to any other product***.
>
> Clearly as emphasized during the regulatory review process, Vascepa's effects go well beyond triglyceride [lowering]. I look forward to expanding this knowledge to other health care professionals.
>
> A significant part of our education process will also emphasize that with an FDA-approved indication, it makes little sense for patients to continue being treated with earlier generation products, which while might have lowered triglyceride levels have all failed to demonstrate cardiovascular risk reduction in clinical studies.
>
> This includes, but is not limited to fenofibrates, Niacin and Omega 3 mixtures.
>
> ***As part of this education process, we will also be emphasizing how Vascepa is different from these other products***.
>
> ***Along the way, we hope that the media and others will cease calling Vascepa a "fish oil product" or else make it clear that Vascepa is quite different in effect from standard fish oil. Otherwise, there is a risk that patients in the general public who need medical health won't learn and understand these important differences. Only Vascepa has been demonstrated to lower cardiovascular events***.

108. On January 15, 2020, Thero participated in the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

I mean this is a drug that we've been developing for over a decade, tremendous science involved with it. And as the guidelines have been stating, the results that we have with the study – with the study of this drug should not be generalized to any other product. There's been a lot of products that have been tried and failed. At this point in time, only Vascepa has succeeded.

* * *

And there's a tremendous amount of science, of course, behind cardiovascular disease, but also a tremendous amount of science behind the multifactorial effects of Vascepa. This is a unique molecule. It's been deemed a new chemical entity by the FDA. It is – it has multiple effects that have not been shown for any other molecule. And both the study that we've done to show those multiple effects and the science behind being able to isolate this molecule, which is a very fragile molecule, and to protect it so that it's stable and unoxidized from the point of manufacturing to administration and the patient involves tremendous science and further differentiates our product from any other product that's out in the marketplace. ***And I'm pleased obviously that, that's been recognized by these medical societies, which emphasize that our clinical results should not be generalized to any other product***.

109. On February 25, 2020, Thero hosted Amarin's 4Q 2019 earnings call and made the following materially false and misleading statements:

I could cite many additional Amarin accomplishments in 2019. Clearly, 2019 was an outstanding year of execution and results. We are now focused on the success of the commercial launch of Vascepa for its new indication. Accordingly, let's shift our discussion to 2020.

Vascepa represents a new class of proven preventative therapy. Vascepa is the first and only drug with this new cardiovascular risk reduction indication. Our launch of Vascepa for this new indication reflects the uniqueness of Vascepa. Such uniqueness is magnified by a backdrop in which all potential competitors that completed or terminated cardiovascular outcome studies have failed to demonstrate that the benefits of their products exceed the risks of such products.

110. On March 2, 2020, Thero participated in the Cowen HealthCare Conference and made the following materially false and misleading statements:

> There's statins, which are terrific, but in terms of on top of statins, there's the LDL-lowering therapies, which PCSK9 is about 15%; acetamide, about 6%. But beyond that, outside of cholesterol management, VASCEPA is tops at 25% relative risk reduction.
>
> ***And this is not by chance. There's a tremendous amount of science***. We have dozens of different publications on the most multifactorial effects of VASCEPA that someone's interested in digging into in more detail, they can see in the publications portion of our website. ***But essentially, this is a unique small molecule, able to get into endothelial cells with unique effects on each of the 8 major factors in the formation of atherosclerosis, something that's not been shown for any other product***. And it's not only just getting to this molecule, but it's a very fragile molecule. Getting – isolating it and keeping it stable for you, which we have done a good job in over multiple years.

111. Defendants' statements alleged in ¶¶99-110 were materially false or misleading at the times they were made, and/or omitted material information required to be disclosed, because they failed to disclose the following adverse information that was known to Defendants or recklessly disregarded by them:

(a) Vascepa was not unique, and Amarin did not invent purified EPA or discover any of its medical characteristics. The attributes and uses for Vascepa that were lauded by Defendants had already been attributed to Epadel, a pharmacological equivalent drug from Japan; and

(b) Amarin did not invent purified EPA or any new use for it, so the Company was not entitled to patent protection for Vascepa. Amarin only received

patents for Vascepa because Defendants withheld material information concerning the relevant prior art from the USPTO examiner during the patent prosecution process, including information about the Kurabayashi Study.

B. False and Misleading Statements Relating to Vascepa's Addressable Market and Financial Prospects Resulting from REDUCE-IT

112. On January 11, 2018, Thero presented at the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

> I showed earlier that the number of patients who have high triglycerides is about twice the number of patients that have high LDL, but yet, the chart here will show that the treatment of LDL is significantly higher than the treatment of other lipids. And that's largely due to a lack of an outcomes study in the triglyceride area. As I pointed earlier, earlier generation therapies weren't – really have limitations to getting there. We think we're going to get there with our outcomes study. The statin market – we're not trying to replace statins, but statins treated about 38 million patients. LIPITOR alone grew to $12 billion before growing – going generic. ***This is the kind of multiple millions of patients that we see as potentially addressable by Vascepa if we get the kind of results that we're working towards in our REDUCE-IT outcomes study.***
>
> * * *
>
> Today, we're selling biomarkers. We're moving towards – selling based upon cardiovascular risk reduction. ***Today, we're taking market share. In the future, we'll be trying to get that 96% of the patients who are not treated at all today. And we see this as being an opportunity that should be measured in the billions***.

113. On September 24, 2018, Amarin held a special call to announce the topline results of the REDUCE-IT study. Thero participated in the call and made the following materially false and misleading statements:

> Fast forward through over a decade and hundreds of millions of dollars of big pharma clinical development to REDUCE-IT. With approximately 25% relative risk reduction on top of statin therapy now demonstrated, we have confirmed that our easy-to-use drug, that's inexpensive, with broad reimbursement coverage, significantly reduces cardiovascular risk. ***It thus has the potential to overcome the limitations of multiple blockbuster prior-generation therapies. It thus has the potential to be a significant blockbuster and help millions of patients reduce cardiovascular risk on top of standard-of-care statin therapy***.

114. On November 18, 2018, Amarin filed a Form 8-K with the SEC, signed by Thero, and included the following materially false and misleading statements attributed to Thero:

> "***The landmark results of the REDUCE-IT study present an important opportunity to improve the practice of medicine with respect to preventative cardiovascular care. We believe that these outcomes study results position Vascepa to address a significant unmet medical need and could be considered the most significant breakthrough in preventative cardiovascular care since the advent of statin therapy decades ago. We are very excited about the potential for Vascepa to help millions of patients and we are acting accordingly to expand on our established commercial foundation, including existing broad managed care coverage and extensive key opinion leader support***."

115. That same day, Thero hosted Amarin's 3Q 2018 earnings call and made the following materially false and misleading statements:

> ***[T]he REDUCE-IT results positions Vascepa to lead a new paradigm in patient care beyond cholesterol management. They also position Vascepa to be first-to-market in addressing a large unmet medical need***. Cholesterol management lowers cardiovascular risk from 25% to 35%, leaving 65% to 75% residual cardiovascular risk. It is the substantial residual risk we seek to address with Vascepa. ***We believe that these clinical results position Vascepa to provide a new layer of***

> ***cardioprotective benefit, which may potentially help millions of patients in United States and internationally***.
>
> * * *
>
> While ***we do believe that REDUCE-IT results will help transform Vascepa into becoming a multibillion-dollar brand***, we intend to wait until healthcare professionals better appreciate the results for the REDUCE-IT study and better appreciate the existing managed care coverage in affordable pricing of Vascepa before we provide revenue guidance. Rather this reference is made to express that the bullish steps we took prior to REDUCE-IT results help position us for continued commercial success. Following REDUCE-IT success, we have been in an active dialogue with companies in our supply chain as well as with certain companies that might be added to our supply chain. To ensure that we can further increase our supply capacity.
>
> * * *
>
> We anticipate supporting various additional medical education programs in Q4 and beyond. We remain optimistic that the REDUCE-IT results will offer ***in a new treatment paradigm*** to address the large, unmet need of combating the residual risks of 65% to 75% that remain after statin treatment. ***The market is potentially large, it's tens of millions of adults are at cardiovascular risk that cannot be addressed by cholesterol management alone***.

116. On December 5, 2018, Thero participated in the Citi Global Healthcare Conference and made the following materially false and misleading statements:

> [S]o Amarin launched Vascepa in 2013 for a[n] important but niche indication, an indication for patients based upon a biomarker of triglycerides of greater than 500 mg per deciliter, which is an indicated associated with pancreatitis. ***We have known that what docs really want for the broader application was outcomes data in the cardiovascular space, much bigger population, roughly 1 in 4 adults in the United States have elevated triglycerides, but fewer than 4% of those patients are treated with any therapy because, as Joel was citing earlier, earlier-generation therapies have all failed***. So now with outcomes data, we will be pivoting from – actually continuing to promote for the current

indication, but also educating physicians relative to the effects of the drug based upon this outcomes study. That will be a multiple-stepped approach. So we are looking for label expansion and assuming a favorable outcome there. After we get label expansion, we will be doing a full launch of the drug to health care professionals and to consumers, which will include expanded sales force and DTC promotion, television and all those kinds of things, that's still roughly a year away.

* * *

The real measure here isn't going to be the number of docs that prescribe it, I think it's going to be very easy to convince physicians that this data is terrific and they ought to be prescribing it. The real measure is going to be do they prescribe it on 1% of their patients, we can make a lot of money and help a lot of patients at 1% of 90 million patients, right. So is it 5% of their patients, we'll – that will be a really great benefit to society and you guys would all be extremely happy if it got to that way. ***Or is it all 25%, and we're about twice but that's about $80 billion. I don't think we'll get there, but that's the size of the potential opportunity***. But that level of penetration ***– I heard some people saying, well, jeez, why wouldn't you prescribe it. The drug's safe, it's affordable, it provides a 25% risk reduction, why wouldn't you prescribe it?*** We'll be measuring all of these things, but it's still very early here just 3 weeks after the data.

117. On January 9, 2019, Thero participated in the JPMorgan Global Healthcare Conference and made the following materially false and misleading statements:

We believe that at Amarin, we have pioneered a solution which provides significant preventative cardiovascular risk reduction beyond cholesterol management. . . . We will be pursuing a[n] expanded indication with the FDA for cardiovascular risk prevention, and we believe this is a multibillion-dollar opportunity.

* * *

> ***The drug has already been prescribed over 4 million times. That's based upon a niche of an important indication of triglycerides greater than 500. This new opportunity is certainly much larger***.

118. On May 1, 2019, Amarin filed its quarterly report with the SEC on Form 10-Q for 1Q 2018, signed and certified by Thero and Kalb, and made the following materially false and misleading statements:

> In contrast, a three-year period of exclusivity under the Hatch-Waxman Amendments is generally granted for a drug product that contains an active moiety that has been previously approved, such as when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly, ***we expect to receive three-year exclusivity in connection with any future regulatory approvals of Vascepa, such as an approval sought based on positive REDUCE-IT outcomes study results***. Such three-year exclusivity protection precludes the FDA from approving a marketing application for an ANDA, a product candidate that the FDA views as having the same conditions of approval as Vascepa (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Vascepa as the reference product, for a period of three years from the date of FDA approval.

119. On May 29, 2019, Amarin filed a Form 8-K with the SEC, signed by Thero, and included the following materially false and misleading statements attributed to Thero:

> "We expect earlier approval of an expanded indication for Vascepa to lead to faster improvements in care for millions of patients with residual cardiovascular risk after statin therapy . . . . These patients will be the focus of our planned expanded REDUCE-ITT M promotional efforts. We are very pleased that the FDA has accepted our application and granted it priority review. ***We believe the unprecedented REDUCE-IT results position Amarin to lead a transformative change in clinical practice for preventative treatment of cardiovascular***

> ***disease, the leading cause of death for both men and women in the United States. Our plans to significantly expand promotion of Vascepa following label expansion are being accelerated to reflect the upcoming PDUFA date***."

120. On June 12, 2019, Thero participated in the Goldman Sachs Global Healthcare Conference and made the following materially false and misleading statements:

> We have submitted for approval. We have received priority review designation by the FDA with a PDUFA date of September 28 of this year. And with that, we think that we can transition this product from our current niche indication, which is important, but niche at treating patients with triglycerides greater than 500 to ***moving into an indication for cardiovascular risk prevention, which is a multibillion-dollar opportunity in the U.S. and globally***.
>
> * * *
>
> ***There is no therapy in the market to address what we are addressing with this therapy, and there are potentially tens of millions of patients who could potentially benefit. There's about 90 million people in the United States alone who have triglycerides of 135 mg per deciliter or greater, and about 15 million of those patients are already on statin therapy and still have those elevated trigs and other risk factors.***

121. On July 2, 2019, Amarin filed a Form 8-K with the SEC, signed by Thero, and included the following materially false and misleading statements attributed to Thero:

> "We are pleased with the progress made to date, including the significant revenue growth we've achieved for Vascepa . . . . ***We anticipate Vascepa revenue growth to accelerate further after label expansion approval and with a larger sales team, and then again after we commence promotion of Vascepa for cardiovascular risk reduction on television and through other media. We are preparing for a robust launch of REDUCE-IT data with the aim of helping physicians***

> ***improve patient care for millions of patients with residual cardiovascular risk after their cholesterol is controlled, as identified by elevated triglycerides***."

122. On July 31, 2019, Amarin hosted its 2Q 2019 earnings call. Kalb participated on the call, and made the following materially false and misleading statements:

> As announced late last week and earlier this week, we completed a follow-on equity offering raising $460 million before fees and expenses. These proceeds, when added to our June 30 cash balance, bring total cash and equivalents to over $600 million, which provides us with the financial resources needed to robustly and confidently execute on our commercial launch plans aimed at helping millions of patients. ***With the success of our launch of Vascepa for this important new indication, we believe that Amarin will create growth and significant shareholder value***. We elected to complete this financing prior to label expansion in order to not be restrained or unnecessarily vulnerable on our launch of Vascepa, while also removing what we believe was a growing financing overhang which – overhang, we believe, was likely to grow as we got closer to label expansion, if it had not been addressed.

123. On September 4, 2019, Thero participated in the Citi Biotech Conference and made the following materially false and misleading statements:

> ***[W]e're working to be at a support multiple billions in revenues, and we're using a strategy that has multiple suppliers competing against themselves***. We saw an earlier generation products where they had a single supplier that, at least in our view, by having a single supplier, it didn't challenge that supplier to stay current and most efficient in its processes. So by having multiple suppliers, we are challenging those suppliers to increase efficiency and continue to lower price but also to increase volume. We came into 2019 in a position whereby if all our – if we were purchasing all of the capacity that our suppliers could produce that we could have supported revenues this year of about $1 billion, that wasn't our guidance.

> Our guidance coming into the year with revenues of about $350 million. We subsequently increased that guidance to $380 million to $420 million for this year. In parallel, we have been working with our suppliers, and they are on track to being able to support significant multiples of the billion dollars in capacity that we came into this year with – while hoping to also continue to improve albeit modestly the efficiency of production. This is a challenging product to manufacture, once you master it, repeating it's relatively straightforward. But it is not a simple product to manufacture.

124. During the same conference, Thero had the following exchange with an investment analyst in which he made materially false and misleading statements:

> [Joel Lawrence Beatty, Analyst, Citigroup:] And maybe another way of asking about the potential labeling for Vascepa in the U.S., what specific aspects of the label are most important for supporting the growth of sales?
>
> [Thero:] So I think most important is that it'd be a cardiovascular risk reduction indication today or approved for is an important but niche indication for treatment of patients with triglyceride levels greater than 500 mg per deciliter, which is a population of patients at risk for pancreatitis in the U.S. about 2 million to 4 million patients with that level of risk. In the cardiovascular risk reduction indication, if we look at patients, for example, with triglyceride levels of 135 mg per deciliter or greater. There's data out there suggesting that cardiovascular risk begins to increase as triglyceride unit level is lower than 100 mg per deciliter. ***But if we just look at the population of patients with triglycerides from 135 and above, that's about 90 million people in United States. If we look at statin treated patients with elevated triglycerides 135 and above, that's about 15 million patients in the United States. So these are big numbers, and with a cost-effective therapy like Vascepa we see this as being the first opportunity to treat these patients with a proven therapy.***
>
> * * *
>
> I envision that with Vascepa, as we get label approval and physicians begin to become more knowledgeable of and then use it, they will start with their highest risk patients. There will be statin-treated

> patients, so statins are proven, they've been out in the marketplace for 25 years, and we're not trying to replace statin therapy, rather we're trying to deal with the factorial risk that exists beyond cholesterol management.
>
> So they'll probably start with diabetic patients, they'll probably start patients with established cardiovascular disease, and then probably over time migrate to things like pre-diabetic patients or the patients with other cardiovascular risks.
>
> Again all these are large populations or subgroups of that number. And all these really don't have any proven therapy. ***Really they do not have any proven therapy so Vascepa offers an opportunity to provide great help to these millions or tens of millions of patients.***

125. On November 5, 2019, Amarin filed a Form 8-K with the SEC, signed by Thero, and included the following materially false and misleading statements attributed to Thero:

> "Our aim is to help as many patients as possible with Vascepa. Accordingly, we are pleased to witness the growth in Vascepa usage as reported in the third quarter. ***These recent results are laying the foundation for our future growth as we seek to make Vascepa a new standard of care for use in appropriate at-risk patient populations based on REDUCE-IT***."

126. On December 16, 2019, Amarin hosted a special call. Kalb participated in the call and made the following materially false and misleading statements:

> On Friday, we provided the following update to that guidance and also issued our first quantified guidance for 2020 as follows. In 2019, we have increased total net revenue guidance to a range of $410 million to $425 million. Midpoint of this new full year guidance is $417.5 million and represents an increase of approximately 82% over full year 2018. As a reminder, we recorded total net revenue of $286.5 million for the 9 months ended September 30, 2019, resulting in a range for Q4 2019 total net revenue of $123.5 million to $138.5 million.

> Predicting wholesaler order levels around year-end is tricky. Our guidance for 2019 reflects our positive progress quarter-to-date in the fourth quarter of 2019. It does not assume any significant change in orders during the second half of December.
>
> ***At this time, we are projecting that total net revenue for 2020 will be in the range of $650 million to $700 million, mostly from sales of Vascepa in the United States***.
>
> * * *
>
> The current price of Vascepa is similar to the price of atorvastatin, brand name, Lipitor, for which annual revenue exceeded $10 billion before it went generic. Affordable pricing works well for that drug, and we are seeking to follow their model.
>
> ***Beyond 2020, we believe that Vascepa total net revenue will grow to reach multiple billions of dollars. However, the history of other therapies for chronic conditions suggest that growth builds over multiple years***.
>
> Accordingly, at this time, we are not providing guidance regarding annual revenue levels beyond 2020.

127. On the same call, Thero made the following materially false and misleading statements:

> I have received or been copied on many congratulatory e-mails from others, knowing the company's dedication perseverance and focused execution, which have been keys to our success in helping to bring this to market, a product that can address the pervasive and deepening societal problem of cardiovascular disease. We are very proud of our accomplishments. However, we very much understand that the job is not done. ***We are committed to making Vascepa a multibillion-dollar brand and a standard of care for patients with persistent high cardiovascular risk***.

128. On January 7, 2020, Amarin filed a Form 8-K with the SEC, signed by Thero, and made the following materially false and misleading statements:

> Amarin anticipates total net revenue in 2020 will be in a range of $650 to $700 million, mostly from sales of VASCEPA in the United States. The guidance remains unchanged from the total net revenue guidance issued by the company on December 13, 2019.
>
> ***Beyond 2020, Amarin reiterates that it believes that VASCEPA total net revenue will grow to reach multiple billions of dollars. The history of other therapies for chronic conditions suggests that growth builds over multiple years. At this time, the company is not providing guidance regarding annual revenue levels beyond 2020***.

129. On January 15, 2020, Thero participated in the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

> One of our goals for this new year is to make Vascepa a new standard of care. We have studied Vascepa in patients who were treated with all contemporary therapy, well controlled for hypertension, diabetes and cholesterol. The drug works, the drug works well. And I'm referring, of course, to Vascepa or icosapent ethyl. . . .
>
> . . . [A] month ago, the FDA approved as the first ever drug for an indication for addressing patients with persistent cardiovascular risk beyond statin therapy, and ***that was based upon the landmark results of our cardiovascular outcome study, REDUCE-IT***. And pursuant to that, we are doubling the size of our sales force. We have the potential to help millions of the patients here in the United States. This is a global opportunity. Before this indication expansion, Vascepa had already been used to treat over 8 million patients based upon our initial, more niche indication. ***And we think here launching with what is already good managed care coverage and sole share of voice and no immediate competition positions us to grow significantly and make this a multibillion-dollar product and household name***.

130. On February 25, 2020, Amarin filed a Form 8-K with the SEC, signed by Thero, and included the following materially false and misleading statements attributed to Thero:

> "2019 was a transformational year for Amarin and for preventative cardiovascular patient care . . . . VASCEPA became the first and only FDA approved therapy for its new cardiovascular risk reduction indication. ***Our record 2019 revenue levels, together with the recent FDA-approved VASCEPA label expansion, excellent employees and strong third-party support, all position Amarin for considerably further growth in 2020 and beyond. Based on feedback thus far, we are confident that healthcare professionals will appreciate the clinical effectiveness and safety profile of VASCEPA and that they will agree that many patients can benefit from this unique product***. In 2020, we plan to prioritize market education and promotion to expand the usage of VASCEPA for the benefit of at-risk patients. ***This is the advent of a new era in preventative cardiovascular care***."

131. On February 25, 2020, Thero hosted Amarin's 4Q 2019 earnings call and made the following materially false and misleading statements:

> Regarding our sales force in the United States, we are now close to doubling its size. ***As previously described, we believe that a U.S. sales force of 800 sales representatives, supported by our other promotional activities, is positioned to make Vascepa a multibillion-dollar brand***. Our sales team enthusiastically believes this as well. We hired and trained new sales representatives in waves during December, January and February. At this point, nearly all of the targeted 800 sales representative positions have been filled. A small number of newly hired sales representatives are still undergoing training. They should be in the field soon. As is the nature of hiring, some people don't succeed and need to be replaced. Overall, we are impressed with the attitudes, intelligence, passion and experience of the members of our sales team.

132. On March 2, 2020, Thero participated in the Cowen HealthCare Conference and made the following materially false and misleading statements:

> We are – today, I believe we are transforming preventative cardiovascular care. We're also transforming what we are as a company. ***We're moving from a niche sales force with an indication based upon a changing a biomarker to a company with a large preventative care, primary care sales force focusing in on cardiovascular risk reduction.***

> ***And we think we're going to help many patients, hopefully, millions of patients***.

133. On April 13, 2020, Thero hosted Amarin's preliminary 1Q 2020 earnings call and made the following materially false and misleading statements:

> We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they have turned down such approaches for various reasons, including that they don't have excess capacity. We don't have perfect visibility of the dynamics that could contribute to the timing and capacity of a generic launch, but we either have plans in place already or we are rapidly putting plans in place for a range of possible scenarios. ***We believe that there is an opportunity for shareholders to benefit under the most likely of these scenarios***.
>
> * * *
>
> ***Overall, Amarin is confident that we will find pathways to create value for its shareholders from our operations in the United States and internationally***. We have overcome greater challenges in the past. Amarin is well capitalized. Our revenues grew over 100% in Q1 of 2020 compared to last year. We have great people. ***We have a unique product with unprecedented clinical results, and we are addressing a potentially huge market need. Although we don't yet have all the answers, if we don't lose sight of our objectives, we will find ways to succeed.***

134. On January 12, 2021, Thero presented at the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

> ***VASCEPA is rapidly becoming a new pillar in preventative cardiovascular care. We have the drug, the signs, the people and the resources to, and we believe, being quite successful in the U.S., Europe and rest of the world***.

135. On February 25, 2021, Thero hosted Amarin's 4Q 2021 earnings call. Thero and Kalb made the following materially false and misleading statements:

[Thero:] We are aware of generic competition. We take all competition seriously. Nonetheless, we think that it would be a disservice to patient care in the United States and irresponsible to our employees and investors if we cease branded product promotion in the face of generic competition in this atypical generic market.

Without further market education, use of VASCEPA will be unnecessarily limited and patient care will suffer. If, for example, VASCEPA was a household name that had been promoted for a decade or if VASCEPA was a high-priced product, our decision to continue promotion might be different. ***We believe that the upside potential from continued market expansion in the United States remains considerable.***

* * *

[Kalb:] John noted our record levels of net revenue in both the full year and the fourth quarter of 2020. These increases were driven primarily by increased volume of VASCEPA sales to customers in the United States. The net price of VASCEPA, while it increased modestly in 2020, has essentially remained flat for many years. It is not possible to quantify the impact of COVID-19 on our 2020 net revenue, although, we are certain that such impact was significant. ***Additionally, while it is also not possible to quantify the impact of the generic product launched in November 2020 on our net revenue, we do not believe such launch had a material impact.***

* * *

[Thero:] ***With respect to why we believe that we can grow faster than generics, that's a complex topic. And we begin with the fact that this really is very much an atypical generic market, atypical in the sense that for the generic that's launched, greater than 93% of the use is off-label***.

I discussed VASCEPA [is on a] mature market, most people don't know about it. Yet ***this is a multibillion-dollar opportunity that we think we're – we've just launched into***, 13 months ago we just began the launch. We're focusing on patient education and this is not an expensive product. So it's not like the generics coming in, they'll be rushing off to the generic because it's less expensive. To the contrary, we've seen managed care coverage continue to expand.

> ***And then the manufacturer of this product requires significant investment that Amarin has made and supported over multiple years to create efficiencies, but the lead times here for product suppliers, it's long and then expensive. So it probably contributes to why only 1 of the 3 approved generics have launched at this stuff point in time***. And the one that has commented that their gross margins on that product is lower than what it is for other products because of the high – relatively high cost for the production of this high-quality complex product to manufacture.

136. On March 1, 2021, Thero participated in the Cowen Healthcare Conference and made the following materially false and misleading statements:

> [W]e try to operate in a thoughtful way with lots of different scenario planning. We could – if we thought it was the right path, we could launch an authorized generic, probably have it in the market this week if we were to so choose. Based upon our analysis, we don't think that, that is the right move for our shareholders. We certainly don't think that, that is the right move for patient care because in a generic scenario that would bring on of cutting costs, not doing promotion, clearly, the generic companies aren't spending money on promotion or on R&D. The awareness of this life-saving drug will never reach its fulfillment. And this drug just launched in January of last year. ***And as we look at this, we still believe that this is potentially a multibillion-dollar opportunity in the United States with millions of at-risk patients and awareness of VASCEPA amongst doctors because we really hit up against COVID in the launch, doctor awareness is very low, at-risk patient awareness is even lower***. So this is a very atypical generic situation where the generic is launching into certainly not a mature market, also launching into a market where, by third-party analysis, the cost of VASCEPA is not high.

137. Defendants' statements alleged in ¶¶112-136 were materially false or misleading at the times they were made, and/or omitted material information required to be disclosed, because they failed to disclose the following adverse information that was known to Defendants or recklessly disregarded by them:

(a) Amarin would not be able to sell Vascepa to millions of patients for billions of dollars if it lost patent protection for its product. Without patent protection, Amarin would have to compete with generic manufacturers of purified EPA, which had already submitted ANDA filings to sell competing drugs in the U.S. These generic drugs would take market share from and drive down prices for Vascepa, destroying Amarin's ability to earn meaningful revenue from its U.S. sales;

(b) The loss of patent protection would dramatically undermine the positive REDUCE-IT results concerning Vascepa's treatment for cardiovascular risk, because physicians could prescribe generic versions of Vascepa to patients to address that risk, rather than prescribing Vascepa; and

(c) Amarin did not invent purified EPA or any new use for it, so the Company was not entitled to patent protection for Vascepa. Amarin only received patents for Vascepa because Defendants withheld material information concerning the relevant prior art from the USPTO examiner during the patent prosecution process, including information about the Kurabayashi Study.

C. False and Misleading Statements Relating to Amarin's Patent Litigation

138. On November 1, 2018, Kennedy participated in Amarin's 3Q 2018 earnings call and made the following materially false and misleading statements:

> [Louise Alesandra Chen, Analyst, Cantor Fitzgerald:] [W]e get a lot of questions on the IP for Vascepa and if you could let us know what the

next steps are with respect to trials and anything else that you are pursuing there, that will be great.

* * *

[Kennedy:] Sure, thanks Louise, for the question. But just as a big piece of reminder ***our patents go out to 2030***, we do have settle agreements with Teva which allows them to enter in second half of 2029, the end of litigation goes on with two additional litigations, and we're in that is at in August of this year we just did – ***I've got a claim construction ruling that is the Markman ruling, where the definition of the claims are determined by the judge after advocacy on both sides and that went very favorably for us***. We won all the terms with the exception of one, which we think has no significance. Reminded that the claims that we have in the patents covered method of use for treating really high triglycerides with the surprising and expected results of lowering traits without raising LDL, and with those who have been in touch with us for a while, remember well back in 2012 the constitutions of those patents when they were dubbed at the most watched patent prosecutions on Wall Street, and there was a lot of back-and-forth with the patent office and they were reviewed not only by the examiner but by the examiner supervisor, by quality assurance specialist, by quality assurance specialist's supervisors, and were part of what was then a special application warning system, which was an elite group of reviewers at the patent office that reviewed less than 0.04% of applications because of the high-profile nature of the applications. And that was mostly focused on the inventive nature of the subject matter at the patents. And we emerged from that, of course, with the patents there that are issued in the litigation. And so as we look forward to in this litigation, we expect the trial in the second half of 2019 and where we are right now, is that we haven't even finished the fact discovery cutoff. So at the point with generic is still going through learning about invention – at the invention and all that. ***So we're somewhat relatively in the early stages having had – again that favorable Markman ruling. So we feel pretty good about that. And there's really nothing significant fill up we've seen from – on the outside just wait until really the second half of next year***.

139. On December 5, 2018, Thero participated in the Citi Global Healthcare Conference and made the following materially false and misleading statements:

> [Joel Lawrence Beatty, Analyst, Citigroup:] A question about intellectual property. In the conversation of [metformin] and regulatory exclusivity run out in 2020, but it seems as if there can be a runway well beyond that for Vascepa in the U.S. Could you tell us a little bit about what gives you confidence in that?
>
> [Thero:] So the protection of Vascepa is really at 3 levels these days. One is it is difficult to manufacture and we think we have economies of scale there. Two is, as you mentioned, there is regulatory exclusivity that goes into 2020, that's based upon the NCE status of our product and the last is the patents. And we now have over 60 patents on the product. ***There are ANDA filers. Any good product gets ANDA filers. It'd be almost insulting if they weren't, I guess.*** There were 4. One of them dropped out fairly early. Another was Teva, they settled. They could come into the market in August of 2029. So about 11 years from now. The other 2, Hikma and Dr. Reddy's, continue in the litigation process. There's been no court date set yet. There have been Markman hearings. ***I think the results coming out of that claims construction was very favorable to us***, at least one of the claimants has acknowledged that if they were to launch, they would be infringing upon our patents. I think it's sort of impossible not to. ***Our patents cover key elements of the label for the product and you can't have a generic without having that label. We intend to defend our patents vigorously***. I think they'd have to, if they are acknowledging that they infringe, they'd have to invalidate these patents ***and these patents were heavily prosecuted through the U.S. Patent Office and as I say, we intend to defend them vigorously***.

140. On March 13, 2019, Thero participated in the Cowen Health Care Conference and made the following materially false and misleading statements:

> [Irina Margine, Analyst, Cowen:] You mentioned the 50 patents for (inaudible). I just wondered if you can briefly summarize what type of patents they are. I think that's the opening question.
>
> [Thero:] Yes, so we have over 50 patents, most of them are not related to the molecules. So what we have is surprising unexpected findings that are specific to our labels. So that for example, and there are – there were 4 ANDA filers, so 1 backed out early, 2 we dealt with and 2 remained in litigation. We've asserted 14 of our Orange Book listed patents against ***those and those patents deal with the surprising and unexpected***

> ***findings associated with our – first of our Phase III studies, which is the genesis of our current label. And they are – the patents are around, I'll just give one example. I think all those patents are terrific, but one example is, patenting the use of highly pure eicosapentaenoic acid for the treatment of patients who had triglyceride levels greater than 500 resulting in triglyceride reduction without increasing cholesterol and that's unique from the perspective that even if you put patients with very high triglycerides on diet, their cholesterol tends to go up. Lovaza, in that population, the cholesterol went up by 49% and consistently, you've seen cholesterol go up in that population. So being able to show something different for that was deemed to be unique and the ANDA filers have acknowledged that where they'd have generic product that they would infringe that patent is central to our – it's central to our label. So that's just an example of 1 claim and 1 patent.***

141. On May 1, 2019, Thero hosted Amarin's 1Q 2019 earnings call and made the following materially false and misleading statements:

> Before beginning the Q&A portion of this call, let me respond to a line of questioning that we hear periodically regarding our ongoing ANDA litigation. ***Our patents expire in 2030***. The public record for the ANDA litigation is available for all to view and many have. As a reminder, there are 2 ANDA filers that remain in the litigation on the original 4. [Apotex] determined not to litigate in the case early on in the proceeding. Rather than continue to litigate, Teva settled with us to enter in August 2029.
>
> There is no IPR proceeding, that is inter partes review, in this case. The statutory 1-year window for IPRs from the end of filers on the relevant patent has expired. While court schedules can change, the current timing suggests that this matter, assuming it is not settled, would go to trial in early 2020. ***We continue to defend our patents vigorously.*** We don't plan to comment further regarding ongoing litigation beyond the above.

142. On June 12, 2019, Thero participated in the Goldman Sachs Global Healthcare Conference and made the following materially false and misleading statements:

> [Thero:] ***We have now over 100 patents internationally, predominantly in the United States, most with expiries in 2030***. And internationally, we have a priority review in Canada with the hope of having it approved there in the fourth quarter of this year. In the Middle East, through our partner, we have application into multiple countries and already have approval in Lebanon, in the United Arab Emirates. In China, we have a clinical trial going on through our partner there. And it is our aim to submit in Europe sometime around the end of this year. ***This is a global epidemic, and this is – we have global rights to the product, and we feel like we're just getting started.***
>
> * * *
>
> [Unidentified Analyst:] John, could you comment on – there's been some talk about generic competition or challenging your patent. Could you talk about your strategy there? And also the production of Vascepa and what type of limits there are out there for you and for others.
>
> [Thero:] Yes. So the question pertains to ANDA filers. This is out in the public record. There were 4 ANDA filers. One of those, Apotex, removed themselves from the process, and one of those is Teva. We did reach a mutually agreeable settlement with Teva that they could enter into the market in the second half of 2019 (sic) [2029] which is a little over 10 years from now. There are 2 remaining filers. ***We have gone beyond the Markman hearing, which is – which I think went largely a – almost entirely in our favor. This is the claims construction hearings. More recently, we've been – the court has allowed us to introduce the results of the REDUCE-IT study and as – which we believe are supportive of the uniqueness of Vascepa.***
>
> ***The – there is a court date scheduled for opening hearings on January 13. If it goes to court, we probably have a decision 2 to 3 months. After that, we've asserted 14 of our Orange Book listed***

patents. They all have expiries in 2030. They all have multiple claims, and we intend to defend those patents vigorously.

This is a unique field. This is not a drug that's easily manufactured. There is Lovaza out there, which is GSK's drug, which I think some of the generics on there probably have lost money as it's been difficult to manufacture and they've had some shortages over time with that drug. Our suppliers have spent tens of millions of dollars. And with their expansions, I'm sure it will get up over to the multiple hundreds of millions of dollars investing in supply, capacity and efficiency. ***The belief that we're going to grow Vascepa into a multiple-billion-dollar opportunity – and, of course, Vascepa is more difficult to manufacture than is Lovaza. So we'll see what happens relative to the end of litigation. I can't make any predictions there other than stating that we intend to defend our patents vigorously, and we like our IP***.

143. On November 5, 2019, Thero hosted Amarin's 3Q 2019 earnings call and made the following materially false and misleading statements:

Before beginning the Q&A portion of this call, I will also touch upon the summary judgment ruling issued by the court hearing, or ANDA litigation, in Nevada on October 29. The litigation is proceeding towards the previously announced trial date of January 18. If this litigation goes to trial, it will be a trial held by a judge, not a jury trial. We are quite pleased with the court's summary judgment ruling. Seeking summary judgment at this stage and end of patent litigation is a common approach for generics to seek an early end to litigation and for both parties to seek to limit the scope of issues at trial. ***The judge ruled against the end of filer's summary judgment motion that sought to end the case at this early stage in their favor and ruled more in Amarin's favor to limit the scope of issues that remain for trial. We see this ruling as strengthening our position in the litigation by eliminating from the case several potential lines of generic argument. As such, the ruling strengthens Amarin's position, should it be determined that case settlement is in the company's best interest.***

We look forward to litigation progressing. Due to the complex nature of patent litigation, we refer investors to the court's order and other court documents for further detail, which can be located through

> the FAQ section of our Investor Relations website. We also refer investors to the Risk Factors section in today's Form 10-Q for detail. We intend to continue to vigorously defend our patents but don't intend to go into more detail on that today.

144. On January 15, 2020, Thero participated in the JPMorgan Healthcare Conference and made the following materially false and misleading statements:

> ***From a data exclusivity perspective, in the United States, we've protected, via patents, 2 different indications. Our initial indication, which is for the trigs greater than 500, is currently subject to ANDA litigation.*** We did settle with Teva, and Teva could come into the market in August of 2029. Litigation continues and is active currently with Dr. Reddy's and Hikma. We believe we'll hear the results of that case somewhere near the end of March of this year. ***Obviously we're confident in the results, which is why we're expanding our commercial infrastructure.***
>
> The new indication of cardiovascular risk reduction is supported by numerous patents, of which over 20 are now listed in the Orange Book.

145. On February 25, 2020, Thero hosted Amarin's 4Q 2019 earnings call and made the following materially false and misleading statements:

> Based on court proceedings, the court's decision on this matter is expected near the end of March. Amarin's commercial plans assume that the courts uphold our patents and otherwise ensure that Amarin retains the exclusivity, which we believe we deserve under the law. Such exclusivity will support Amarin's further promotion and education, leading to expanded use for the benefit of millions of at-risk patients. In my view, it would be a considerable setback to pharmaceutical development and patient care if we do not prevail in this litigation. As we've described before the litigation began, while there is risk in any litigation, ***we believe that our legal arguments are persuasive and should prevail. The U.S. Patent Office was convinced of the appropriateness of our patents, and we believe that the court should conclude similarly.***

146. On March 2, 2020, Thero participated in the Cowen HealthCare Conference and made the following materially false and misleading statements:

> The exclusivity side of things, there is ANDA litigation going on at the moment, focus for many shareholders. ***I think we went into the court proceedings there, with understanding that we had persuasive legal arguments. I think we came out of that court without any real negative surprises and an increase in confidence. So relative to our arguments, there's risk involved with any ANDA litigation, but we think that we are in a good position based upon our intellectual property. And certainly, we are positioning ourselves for success here and expansion***.

147. On April 13, 2020, Thero hosted Amarin's preliminary 1Q 2020 earnings call and made the following materially false and misleading statements:

> Regarding the district court ruling and the ANDA litigation, as previously communicated, ***we were surprised and disappointed that the court determined that patent, upon which we relied to build our business, should be considered invalid based upon arguments of perceived obviousness. In doing so, in my view, the court's decision not only did not fully appreciate the importance of VASCEPA as a unique and valuable breakthrough therapy, for which I believe there is considerable evidence, but it also overturned the decision of the U.S. Patent Office, which, earlier, had granted our patents after thorough review of prior arc and after its own consideration of obviousness***. We understand that it is difficult to look back at VASCEPA product development, the genesis of which commenced over a decade ago and past judgment on what was understood by people at the time.
>
> However, I was part of Amarin at that time, but ***I can ensure you that investors and experts did not think that what Amarin was pursuing was obvious***. For example, I recall at that time that Glaxo was looking for a next-generation product for Lovaza. Based upon my recollection of communications with them at the time, they didn't expect to find that solution in pure EPA. Rather, they were like other big pharma companies that had dismissed omega-3s as a solution. Big pharma companies at that time, to the extent that they were focusing in on

cardiovascular disease, were focusing in on statin, CETP inhibitors, making Niacin better tolerated in on fenofibrate, not on treating severely high triglyceride levels.

* * *

The appeal process likely won't focus on much of the content which I just expressed, and therefore, such arguments matter little, ***except as to provide you with some context and support for our broader belief that our patents should have been upheld as inventive and not obvious***.

* * *

For success, we need to effectively persuade the federal judges that the district court opinion is wrong based upon errors of law and fact that bear on its opinion. ***We believe that we have numerous arguments that will contribute to a strong substantive appeal. Many of you have expressed to us examples of arguments that go to a point that could be argued on appeal***. At this time, we are not going to communicate which arguments will be emphasized.

When our appeal is submitted, likely in early May, such arguments will be public. We believe our outside counsel in the district court matter made a convincing case. ***All experienced, independent commentators took a serious look at the record, agree the trial should have resulted in a judgment for Amarin***. Looking forward, we have determined that the importance of this case and appeal calls for the addition to the team of a fresh perspective on the record. The nature of arguing an appeal in this field is specialized. And we have, accordingly, added to our legal team a new lead counsel for this matter, who, like our trial council, is a recognized leader in the field and has won cases of this nature at the Federal Circuit. Our new lead council will work with our in-house team and the team that argued the matter in the district court.

* * *

Based on actions of the generic companies after the court testimony in Nevada, I doubt that they thought that they won the litigation. ***The uniqueness and inventive nature of VASCEPA has been well recognized for years as was well documented in the U.S. Patent Office. There was a unanimous view of those lawyers and analysts reporting on the matter that Amarin had made a winning case at trial.***

> ***The uniqueness of VASCEPA was further evidenced by the success of the REDUCE-IT study and by the early stopping of the competitive study STRENGTH, due to its low likelihood of demonstrating benefits and to numerous accolades for VASCEPA for medical societies and key opinion leaders.***
>
> * * *
>
> We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they have turned down such approaches for various reasons, including that they don't have excess capacity. We don't have perfect visibility of the dynamics that could contribute to the timing and capacity of a generic launch, but we either have plans in place already or we are rapidly putting plans in place for a range of possible scenarios. ***We believe that there is an opportunity for shareholders to benefit under the most likely of these scenarios***.

148. On April 30, 2020, Amarin filed a Form 8-K with the SEC, signed by Thero, and made the following materially false and misleading statements:

> As previously disclosed, Amarin and the defendants in the patent litigation pertaining to the initial indication for VASCEPA in the United States have agreed to expedite proceedings for the appeal of the district court decision. The parties have requested the U.S. Court of Appeals for the Federal Circuit approve an expedited schedule including requested briefing in Q2 2020 and an expedited hearing. This proposed timing should facilitate a hearing in Q3 2020 (or perhaps early Q4 2020) and position the court to rule thereafter potentially in 2020 or in early 2021. ***Amarin believes that it has a strong basis for appeal, which will be set out in its opening brief proposed for filing on May 12th***.

The Form 8-K also included the following materially false and misleading statements attributed to Thero:

> "Amarin's record revenue in Q1 2020 further confirms the value of VASCEPA's new cardiovascular risk reduction indication and reflects that our commercial launch got off to a good start . . . . ***We are regularly receiving positive responses from physicians about VASCEPA and***

> ***witnessing further improvements in already good managed care coverage for VASCEPA supporting the large opportunity for this unique product***. With strong science, great employees and wonderful collaborators, we are highly motivated to improve patient care for the millions of people worldwide who might benefit from VASCEPA while aggressively working to overcome challenges caused by COVID-19 restrictions and patent litigation."

149. That same day, Thero hosted Amarin's 1Q 2020 earnings call and made the following materially false and misleading statements:

> This litigation pertains to patents previously approved by the U.S. Patent Office and relied upon by Amarin in our development of VASCEPA. The patents cover the unique effects of VASCEPA relevant to VASCEPA's initial FDA-approved indication for lowering very high triglyceride levels. At the end of March 2020, the U.S. district court in Nevada declared as invalid the previously issued U.S. patent on the grounds that they were obvious and, therefore, should not have been granted by the U.S. Patent Office. ***If such a decision is allowed to stand, it undermines the protection of VASCEPA upon which Amarin, in good faith, relied throughout the development of VASCEPA. We have filed our appeal to the Federal Circuit. We and our outside counsel believe that we have numerous strong arguments that will contribute to a substantive appeal.***
>
> * * *
>
> ***For reasons described on our April 13 call, it remains stunning that the invention of VASCEPA can now be viewed by anyone as obvious. It wasn't obvious to our competitors or to others in the industry throughout our more than a decade of VASCEPA development and testing. I appreciate that the elegance of our solution may now, in hindsight, appear obvious. However, such is often the nature of innovation. Amarin is vigorously pursuing this appeal. We are doing so fully convinced that the invention of VASCEPA was not obvious.***

150. On August 4, 2020, Amarin filed a Form 8-K with the SEC, signed by Thero, and made the following materially false and misleading statements:

> ***Amarin believes strongly that the lower court judgment was seriously flawed and that it has strong arguments on appeal that could result in a victory for Amarin. If generic companies ultimately succeed at this effort, Amarin anticipates that for an extended period of time a significant portion of the icosapent ethyl market may remain branded due to potential supply volume constraints for high quality, generic versions of VASCEPA. At this time, Amarin is increasing promotion of VASCEPA with the expectation that Amarin will benefit from such promotion under these conditions with or without the launch of generic VASCEPA***.

151. On the same day, Thero hosted Amarin's 2Q 2020 earnings call and made the following materially false and misleading statements:

> Our ongoing appeal to the Federal Circuit in the U.S. patent litigation is in response to the decision in March of this year from the Federal District Court in Nevada, which ruled that the discoveries underlying VASCEPA's patents that protected our initial FDA-approved indication for VASCEPA were obvious. Thus, in effect, the court ruled that the patents upon which Amarin has relied should not have been granted by the U.S. Patent Office. ***This decision was unexpected by everyone, including, we understand, the generic companies involved in the litigation.***
>
> As discussed in the past, we believe that the District Court decision is flawed. Having lived and worked through the early development of VASCEPA prior to the results of the MARINE and ANCHOR clinical studies, ***it is clear to me that the unique effects of VASCEPA were not obvious*** at that time to others outside of Amarin and that it was Amarin's scientific insights developed over years of experience, which led to the successful development of VASCEPA. It was a development path that other scientists and other drug developers had not pursued.
>
> Nonetheless, a decade later, the District Court judge, in trying to go back in time, interpreted matters differently. Unfortunately, the judicial process is such that ***it doesn't matter that I, you or others conclude that the District Court's decision was wrong. It also doesn't seem to matter that this District Court ruling, if allowed to stand, is likely to leave many patients unnecessarily at high risk for major***

adverse cardiovascular events and potentially at unnecessary risk for other medical risks, which VASCEPA may be able to address, in which we are in various stages of investigation. The potential benefits of which are less likely to be realized if VASCEPA becomes generic.

* * *

The Federal Circuit is likely to reach a decision in 1 of 3 categories. ***First, the court could rule in Amarin's favor. Not surprisingly, we clearly think that this decision is the best and most appropriate decision. However, while we believe that we have good legal arguments and that our patents should be upheld and that we have a reasonable shot at winning***, there is no way for us to guarantee that the Federal Circuit will decide in Amarin's favor. Secondly, the Federal Circuit could rule in favor of the generic companies and confirm the District Court decision. Such a decision would be disappointing on many levels. However, we recognize that such a decision is possible, as overturning a lower court ruling has not been easy in the industry historically. Or thirdly, the Federal Circuit could remand the matter back to the District Court for reconsideration by the District Court based on guidance from the Federal Circuit regarding how to properly apply the law and/or how to consider certain facts.

* * *

But regarding the patent side, clearly, we think that the right answer here should be that we win and we then have exclusivity until generics could come into the market in 2029. I think that, that is the right answer. In the event that we were to lose, it's our view based upon information available to us that supply for generic companies would be limited. The supply is limited. There's really not a lot of motivation for them to try to get into a pricing war, in particular, because we would undoubtedly have better cost efficiencies on the manufacturing side. But if you've got limited supply and it's difficult to manufacture, why would you sell that limited supply inexpensively?

152. On November 5, 2020, Amarin filed a Form 8-K with the SEC, signed by Thero, and made the following materially false and misleading statements:

> The third quarter was a productive but challenging quarter for Amarin as total net revenue grew to record levels reflecting increased prescription levels for VASCEPA, despite many patients not yet returning to their doctors' offices for preventative healthcare due to the global pandemic . . . . ***We believe the key court decisions regarding VASCEPA patents related to the triglyceride lowering indication have been wrong and we plan to continue to pursue this matter to the highest level***. Moreover, we believe that because of numerous factors, including that VASCEPA was only recently launched as the first and only drug for its cardiovascular risk reduction indication, that continued investment is justified in market expansion with the expectation that increased revenue and profit can accumulate for Amarin by doing so.

153. That same day, Thero hosted Amarin's 3Q 2020 earnings call and made the following materially false and misleading statements:

> As you know, we are very disappointed that the Federal Circuit upheld the District Court's earlier patent decision. On November 4, 2020, our rehearing and *en banc* petitions were denied. We plan within 90 days of such denial to ask the U.S. Supreme Court to hear our appeal. ***We believe that courts were wrong in their decisions, and we will continue to pursue this matter, although we cannot provide any guarantee of success in this pursuit.***
>
> Unfortunately, the decisions were not only wrong for the reasons we articulated in our litigation, but they also have the effect of harming patient care in the United States as fewer patients may ultimately benefit from VASCEPA.
>
> ***As a reminder, the patent loss for VASCEPA is only in the United States and relates only to the niche VASCEPA indication approved in 2012 triglyceride lowering in patients with severely high triglyceride levels, which is defined by the FDA-approved label and by medical guideline as triglyceride levels greater than or equal to 500 milligrams per deciliter.***

154. Defendants' statements alleged in ¶¶138-153 were materially false or misleading at the times they were made, and/or omitted material information required

to be disclosed, because they failed to disclose the following adverse information that was known to Defendants or recklessly disregarded by them:

(a) Amarin did not invent purified EPA or any new use for it, so the Company was not entitled to patent protection for Vascepa. Amarin only received patents for Vascepa because Defendants withheld material information concerning the relevant prior art from the USPTO examiner during the patent prosecution process, including information about the Kurabayashi Study; and

(b) Since Amarin's patents were issued in error, Amarin would not succeed in its litigation against the ANDA filers or any appeals derived from that litigation.

VI. ADDITIONAL EVIDENCE OF SCIENTER

155. By virtue of the facts set forth herein, it may be strongly inferred Defendants knew or recklessly disregarded that their Class Period statements were materially false or misleading to investors.

A. Defendants' Fraudulent Scheme Revolved Around Amarin's Sole Product

156. During the Class Period, Vascepa was Amarin's sole product. Vascepa was launched in the United States in January 2013 and the Company admitted that "[s]ince our inception, we have devoted substantial resources to our research and development efforts, most significantly our Vascepa cardiovascular outcomes trial, REDUCE-IT." When REDUCE-IT trial results were released in September 2018,

Thero informed investors that Amarin was "doubling the size of our sales force" in order to focus on what Amarin considered a "global opportunity."

157. Because Vascepa was Amarin's only actual or prospective product and was purportedly poised to become a multi-billion dollar drug, Amarin executives exclusively focused on issues concerning Vascepa in their day-to-day work. Indeed, all current and prospective revenue depended upon Vascepa. As a result, every filing with the SEC, conference call with investors, and other public disseminations focused exclusively on the Company's effort to maximize the profitability of Vascepa, including through label expansion, market awareness, and fending off competitors. Accordingly, the Individual Defendants were fully aware of the status of all material matters involving Vascepa – including the viability of its patents. Because maintaining Vascepa's patents was core to the Company's success, the materially false and misleading statements and omissions detailed herein could not have occurred without the Individual Defendants' knowledge and approval.

158. Moreover, the Individual Defendants were all highly sophisticated and in positions to know that their statements concerning Vascepa – including statements regarding the drug's uniqueness, the implications of the REDUCE-IT trial, the Company's health and prospects, and the threat of litigation to Vascepa's patents – were materially false and misleading. For example, by the start of the Class Period, Thero had over 35 years of executive level experience. Prior to becoming CEO,

Thero had previously served as Amarin's CFO from November 2009 to November 2010, when he was subsequently promoted to President and CFO of Amarin. He became President and CEO of Amarin in January 2014. In Amarin's April 15, 2019 Proxy Statement, the Company told investors:

> Since becoming President and Chief Executive Officer, Mr. Thero has played a critical role in selecting, retaining and motivating experienced personnel throughout the Company, repositioning the Company's commercial strategy and tactics resulting in significant product revenue growth, expanding managed care coverage for Vascepa, entering into multiple strategic transactions, ensuring that the REDUCE-IT cardiovascular outcomes study was successfully completed [leading to an expanded FDA-approved cardiovascular risk reduction label for Vascepa], pursuing and achieving multiple remedies through favorable court decisions and achieving the 2018 operating highlights described above.

159. Kennedy joined Amarin in December 2011 as SVP, General Counsel and was named Amarin's Secretary and Chief Compliance Officer in February 2012. He was promoted to EVP, General Counsel and Strategic Initiatives in July 2015. Prior to joining Amarin, Kennedy worked at several pharmaceutical companies, with his most recent stint prior to Amarin at Transcept Pharmaceutical, Inc., where he was the President, General Counsel and Secretary. Kennedy also previously worked in private practice, where he represented large pharmaceutical companies, developing life science companies and venture capital firms.

160. Kalb joined Amarin in June 2016 as SVP and CFO and has over 20 years of financial and accounting advisory experience. He previously served as CFO and

Chief Accounting Officer of Taro Pharmaceutical Industries Ltd. Kalb also has over ten years of experience at Ernst & Young, LLP within the Transaction Advisory Services Group and Audit and Assurance Services Group. Kalb is also a Certified Public Accountant.

161. Additionally, the scienter of the Individual Defendants is imputable to the Company, as the misrepresentations and omissions of Amarin, as alleged herein, were of such a nature they would have been approved by corporate officials sufficiently knowledgeable about the Company to know those statements and omissions were false and misleading.

B. Defendants' Public Actions and Statements Support a Strong Inference of Scienter

162. The Individual Defendants each had particularized knowledge over all aspects of Vascepa, and repeatedly spoke in detail about Vascepa and also their personal knowledge related to the drug via conference calls and other public disseminations with investors during the Class Period, which supports a strong inference of scienter.

163. Thero and Kennedy were executives of the Company during the prosecution of the patents and played an integral role in that process. Thero, who was President of Amarin throughout the patent prosecution process, signed and submitted forms on behalf of Amarin on two separate occasions – on June 20, 2012 and March 26, 2013. The forms were titled "Power of Attorney to Prosecute Applications

Before the USPTO" and they granted Amarin's attorneys the right to prosecute the patent on behalf of the Company. Kennedy, who started as General Counsel during the early stages of the prosecution process, has publicly admitted in his LinkedIn resume that he "[l]ed Amarin's strategy in the successful prosecution of over 40 patents" for Vascepa.

164. Defendants also told investors they had significant personal involvement during the drug's early stages. For example, in the wake of the District of Nevada's ruling in favor of the generic companies, during Amarin's 1Q 2020 preliminary earnings call on April 13, 2020, Thero said:

> We understand that it is difficult to look back at VASCEPA product development, ***the genesis of which commenced over a decade ago*** and past judgment on what was understood by people at the time.
>
> However, ***I was part of Amarin at that time, but I can ensure you that investors and experts did not think that what Amarin was pursuing was obvious***. For example, ***I recall at that time that Glaxo was looking for a next-generation product for Lovaza. Based upon my recollection of communications with them at the time, they didn't expect to find that solution in pure EPA***. Rather, they were like other big pharma companies that had dismissed omega-3s as a solution. Big pharma companies at that time, to the extent that they were focusing in on cardiovascular disease, were focusing in on statin, CETP inhibitors, making Niacin better tolerated in on fenofibrate, not on treating severely high triglyceride levels.

165. Thero also often spoke in detail about REDUCE-IT. On the day that the REDUCE-IT results were released, he said:

> Amarin has always been deeply entrenched in research on omega-3s to support the REDUCE-IT hypotheses. REDUCE-IT commenced in

> 2011. And by the time results of the study are published, Amarin will have spent approximately $300 million for the aggregate cost of the study, with the overwhelming majority of that large cost already spent. We've also invested in early-stage research that shows the unique effects of Vascepa beyond that which we've demonstrated in FDA-reviewed clinical trials.

166. Thero also made numerous statements throughout the Class Period attesting to not only the strength of Vascepa's patents, but also recognizing how important these patents were to investors. For example, during the December 5, 2018 Citi Global Healthcare Conference, Thero stated: "Our patents cover key elements of the label for the product and you can't have a generic without having that label. We intend to defend our patents vigorously." During the June 12, 2019 Goldman Sachs Global Healthcare Conference, Thero proclaimed: "This is a unique field. This is not a drug that's easily manufactured. . . . The belief that we're going to grow Vascepa into a multiple-billion-dollar opportunity." And on Amarin's 2Q 2020 earnings call on August 4, 2020, Thero acknowledged the ANDA Litigation was on the forefront of investors' minds, saying "patent litigation is typically the first topic of inquiry from investors."

167. Kennedy, as Amarin's General Counsel, likewise frequently spoke in detail about the status and history of Vascepa's patent prosecution and litigation during conference calls with investors. For example, on Amarin's 3Q 2018 earnings call on November 1, 2018, he described how:

> [B]ack in 2012 the constitutions of those patents when they were dubbed at the most watched patent prosecutions on Wall Street, and there was a lot of back-and-forth with the patent office and they were reviewed not only by the examiner but by the examiner supervisor, by quality assurance specialist, by quality assurance specialist's supervisors, and were part of what was then a special application warning system, which was an elite group of reviewers at the patent office that reviewed less than 0.04% of applications because of the high-profile nature of the applications. And that was mostly focused on the inventive nature of the subject matter at the patents. And we emerged from that, of course, with the patents there that are issued in the litigation. And so as we look forward to in this litigation, we expect the trial in the second half of 2019 and where we are right now, is that we haven't even finished the fact discovery cutoff.

168. Kalb, as CFO of Amarin, also spoke frequently to investors about the financials concerning Vascepa and the financials related to its patents. For example, on Amarin's 3Q 2019 earnings call on November 5, 2019, Kalb informed investors how the Company's third quarter total revenue was $112.4 million – a "record high for Amarin and an increase of 103% . . . . As expected, nearly all of our total revenue consisted of product revenue from Vascepa sales in the United States." And after the District Court's adverse ruling, on Amarin's 1Q 2020 earnings call on April 30, 2020, Kalb stated, "we are prioritizing our spending to emphasize the following: winning the patent litigation appeal."

169. Thus, Defendants' statements during the Class Period indicated their awareness of, and focus on, issues with respect to Vascepa, including details surrounding its patents and the financial implications resulting from the challenges

affecting the drug. These statements are all highly indicative of Defendants' scienter and that of the Company.

C. The Individual Defendants Dumped over 5.4 Million Shares of Amarin ADSs During the Class Period, Reaping over $83 Million

170. While in the possession of material, non-public information concerning issues related to Vascepa and its patents, Individual Defendants Thero, Kalb, and Kennedy sold over 5.4 million shares of Amarin ADSs at artificially inflated prices, reaping over $83 million in personal proceeds during the Class Period. The following charts summarize Thero, Kalb, and Kennedy's insider sales during the Class Period:

Amarin Corporation plc (AMRN)
9/24/2018 – 4/12/2021

John Thero	Transaction Date	Price	Shares Sold	Proceeds
	11/12/2018	$20.72	5,000	$103,600
	11/12/2018	$19.71	222,158	$4,378,734
	11/12/2018	$18.05	136,422	$2,462,417
	11/12/2018	$19.03	244,031	$4,643,910
	3/4/2019	$21.70	70,673	$1,533,604
	3/4/2019	$21.15	179,327	$3,792,766
	11/11/2019	$17.88	41,741	$746,329
	11/11/2019	$17.05	433,805	$7,396,375
	11/19/2019	$22.65	274,454	$6,216,383
	3/4/2020	$15.99	200,000	$3,198,000
	11/10/2020	$4.13	153,840	$635,359
	11/11/2020	$4.07	413,565	$1,683,210
Total			**2,375,016**	**$36,790,688**

Michael Kalb	Transaction Date	Price	Shares Sold	Proceeds
	9/24/2018	$10.15	79,800	$809,970
	9/24/2018	$10.72	70,200	$752,544
	1/9/2019	$15.26	200,000	$3,052,000
	2/15/2019	$17.58	25,000	$439,500
	2/22/2019	$18.97	50,000	$948,500
	3/1/2019	$22.06	70,801	$1,561,870
	3/1/2019	$22.59	22,075	$498,674
	3/1/2019	$20.89	7,124	$148,820
	7/1/2019	$19.67	50,000	$983,500
	12/16/2019	$25.66	100	$2,566
	12/16/2019	$24.84	1,000	$24,840
	12/16/2019	$23.05	16,400	$378,020
	12/16/2019	$23.81	7,500	$178,575
Total			**600,000**	**$9,779,380**

Joseph Kennedy	Transaction Date	Price	Shares Sold	Proceeds
	9/24/2018	$10.27	884,800	$9,086,896
	9/24/2018	$12.14	139,706	$1,696,031
	9/24/2018	$11.14	55,200	$614,928
	10/1/2018	$17.99	8,400	$151,116
	10/1/2018	$17.47	8,800	$153,736
	10/1/2018	$16.33	33,049	$539,690
	10/31/2018	$20.72	22,707	$470,489
	10/31/2018	$21.37	600	$12,822
	11/30/2018	$17.81	23,306	$415,080
	12/31/2018	$13.49	26,943	$363,461
	1/11/2019	$18.92	3,173	$60,033
	1/22/2019	$17.92	175,300	$3,141,376
	1/23/2019	$17.95	255,779	$4,591,233
	1/24/2019	$17.66	609,115	$10,756,971
	1/31/2019	$17.49	42,624	$745,494
	2/28/2019	$20.72	27,231	$564,226
	4/1/2019	$20.80	1,112	$23,130
	4/1/2019	$20.03	53,060	$1,062,792
	4/30/2019	$18.69	27,230	$508,929
	5/31/2019	$17.92	27,229	$487,944

Joseph Kennedy	Transaction Date	Price	Shares Sold	Proceeds
	7/1/2019	$19.52	54,186	$1,057,711
Total			**2,479,550**	**$36,504,087**

171. The trading activity in Amarin ADSs of the Individual Defendants is completely inconsistent with someone who actually believed that the Company would be better off in the future (as they repeatedly insisted to the public). In reality, the Individual Defendants engaged in massive sell-offs and personally benefitted to the tune of tens of millions of dollars in an effort to jump ship before the scheme fell apart. The insider sales defy reason for someone in the Individual Defendants' positions if not for their possession of material, inside information that they knew would be detrimental to the price of Amarin ADSs once disclosed.

172. Take, for example, Kennedy, the General Counsel of Amarin and therefore the person most acutely aware of the Company's legal issues. Kennedy made statements to investors during the Class Period regarding the security of the Company's patents and Defendants' confidence of success in the litigation against the generic manufacturers. For example, on November 1, 2018, in response to an analyst's question about "next steps" with respect to the patent litigation for Vascepa, Kennedy reassured investors that "just as a big piece of reminder our patents go out to 2030," and that the ANDA Litigation was going "very favorably for us."

173. In the two years leading up to the Class Period, Kennedy sold only 580,116 shares of Amarin ADSs for a profit of $2,138,688. But the day the

REDUCE-IT trial results came out, he sold 1,079,706 Amarin shares – 83.21% of his holdings at that time – for over $11 million in profits. And the sales did not end there. From the time the REDUCE-IT results were announced until the District Court of Nevada ruled in favor of the generic manufacturers, Kennedy sold 89.19% of his holdings, disposing of 2,479,550 shares for $36,504,087 during the Class Period – with all of the sales occurring prior to the District Court's adverse ruling on Amarin's Vascepa patents.

174. Kennedy was not the only Individual Defendant to capitalize on the REDUCE-IT results the day they were released. On the same day results were announced, Kalb sold 150,000 shares – 90.91% of his holdings of Amarin ADSs at that time – for a profit of $1,563,514. Kalb would go on to dispose a total of 600,000 shares – or 65.07% of his holdings of Amarin ADSs – for a profit of $9,779,380. All these sales occurred after the REDUCE-IT results were announced, but before the District Court's adverse ruling on Amarin's patents. He did not sell again during the Class Period. Kalb also did not sell any shares of Amarin ADSs in the two years prior to the start of the Class Period. While dumping these shares and enjoying his windfall, Kalb would continue to mislead the market. For example, on July 31, 2019, Kalb touted to investors how "[w]ith the success of our launch of Vascepa for this important new indication, we believe that Amarin will create growth and significant shareholder value." And on December 16, 2019, the same day Kalb told investors

"[b]eyond 2020, we believe that Vascepa total net revenue will grow to reach multiple billions of dollars," he sold 25,000 shares of Amarin ADSs for a profit of $584,001.

175. Thero also obtained a windfall during the Class Period, having sold 24.30% of his holdings, or 2,375,016 shares, for a profit of $36,790,688 from the sale of artificially inflated Amarin ADSs. Thero reaped this windfall primarily from the sale of Amarin ADSs between the announcements of the REDUCE-IT results until the day the District Court ruled in favor of the generic manufacturers, having sold 1,807,611 shares of Amarin ADS for a profit of $34,472,119 during that time period. Like Kalb, Thero had not sold any Amarin ADSs in the two years prior to the start of the Class Period.

176. While raking in tens of millions of dollars from the sale of artificially inflated Amarin ADSs during the Class Period, Thero continued to mislead the market. For example, during Amarin's 3Q 2019 earnings call on November 5, 2019, Thero updated investors on the patent litigation, telling the market: "We are quite pleased with the court's summary judgment ruling" because it "strengthens Amarin's position, . . . [w]e look forward to litigation progressing." And yet, despite these assurances to the market, just six days later Thero would sell 475,546 shares of Amarin ADS for a profit of $8,142,704. Eight days later he sold another 274,454 shares for a profit of $6,216,383.

177. In sum, while Thero, Kalb, and Kennedy were disseminating false and misleading statements to the market throughout the Class Period, telling investors Vascepa would earn "multiple billions" of dollars in revenue, that the Vascepa patents would extend "out to 2030," and that they "look forward to litigation progressing," these same Individual Defendants were concurrently selling almost all of their holdings of Amarin ADSs during the Class Period – with the majority of the sales occurring before the District Court's adverse ruling against Amarin.

D. Executive Departures Support a Strong Inference of Scienter

178. The abrupt "retirement" of two of the three Individual Defendants shortly after the last alleged disclosure further supports a strong inference of scienter. On April 12, 2021, Amarin announced the retirement of Thero as President and CEO and the appointment of the Company's SVP and Head of Commercial for Europe, Karim Mikhail ("Mikhail"), as his successor, effective August 1, 2021. Mikhail previously spent more than 20 years at Merck, and upon announcing Mikhail's accession, Amarin touted how "he was responsible for reversing the business' decline in the U.S. market and globally." The decision to hire Mikhail in 2020, as well as his elevation to President and CEO, are strong indicators that the Company and its senior management believed Thero was to blame for the dramatic decline in the value of the Company, which left Amarin and its investors in ruin while Thero became over $36 million richer.

179. Later that same month and shortly after the end of the Class Period, on April 29, 2021, the Company's EVP, General Counsel and Strategic Initiatives, Kennedy (age 54) also announced his "retirement." Like Thero, Kennedy had amassed an immense amount of wealth while the Company and its investors suffered dramatic financial losses.

E. Defendants' Certifications Pursuant to the Sarbanes-Oxley Act of 2002 Demonstrate Scienter

180. Within the Forms 10-K and 10-Q filed with the SEC by Amarin during the Class Period, Thero and Kalb certified, pursuant to the Sarbanes-Oxley Act of 2002, that they were "responsible for establishing and maintaining disclosure controls and procedures" and that such controls and procedures were designed "to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared."

VII. SCHEME LIABILITY

181. Defendants engaged in a scheme to put profits and self-interests over their obligations to investors by knowingly or recklessly omitting the true state of the Company's patent protection for its sole product, Vascepa, in order to sell their personal shares at a premium price. This conduct caused the price of Amarin ADSs to trade at artificial levels during the Class Period, as the market was unaware that, in fact, Amarin would not have exclusive access to the market for purified EPA, but

would have to compete with generic manufacturers of the product. Each Defendant is liable as a participant in the fraudulent scheme described herein.

VIII. LOSS CAUSATION

182. The market for Amarin's ADSs was open, well-developed, and efficient at all relevant times. Throughout the Class Period, Amarin's ADSs traded at artificially inflated prices as a direct result of Defendants' materially misleading statements and omissions of material fact, which were widely disseminated to the securities market, investment analysts, and the investing public. Plaintiffs and other members of the Class purchased or otherwise acquired Amarin ADSs relying upon the integrity of the market price for Amarin ADSs and market information relating to Amarin.

183. When the relevant truth began to emerge, the price of Amarin's ADSs declined immediately as the artificial inflation was removed from the market price of the securities, causing substantial damage to Plaintiffs and the Class.

184. On March 30, 2020, Amarin announced that "the United States District Court for the District of Nevada[] rul[ed] in favor of the generic companies in the company's patent litigation against two filers of abbreviated new drug applications, or ANDAs, for Amarin's VASCEPA® (icosapent ethyl) capsule franchise." The District Court ruled the patents had been granted in error and specifically noted that "while the Patent Office found that a decrease in Apo B was an unexpected benefit constituting a

valid secondary consideration, the Patent Office's examiner did not consider Kurabayashi." In direct response to this news, Amarin's ADS price plummeted by more than 70% to close at $4.00 per share on March 31, 2020, on heavy trading volume. In stark contrast, the NASDAQ Composite Index decreased by .95% and the NASDAQ Biotechnology Index decreased by .93%.[4]

185. Even Thero conceded the negative impact that the March 30, 2020 disclosure had on the price of Amarin ADSs, telling investors during Amarin's preliminary 1Q 2020 earnings call on April 13, 2020: "First, I want to express my gratitude to our many investors who, despite losing money after the district court's surprised negative decision on our ANDA litigation, reached out to Amarin."

186. Analysts also recognized that investors had learned material information about the infirmities in Vascepa's patents. As Seeking Alpha ("SA") news editor Stephen Alpher noted in an article titled "Amarin plunges after court decision on Vascepa" on March 30, 2020, the Company "has lost its patent battle against generics." Similarly, an analyst for Roth Capital Partners noted on March 31, 2020: "AMRN share price suffers from loss on ANDA litigation . . . . Yesterday's patent

[4] Amarin cites the NASDAQ Composite Index and the NASDAQ Biotechnology Index as the most appropriate indices that Amarin should be measured against. The NASDAQ Biotechnology Index is an index of U.S. quoted biotechnology and pharmaceutical companies.

ruling and loss now puts a significant wrench into AMRN's commercial Vascepa plan for the U.S."

187. To allay investor concerns, during the April 13, 2020 preliminary earnings call, Thero provided reassurance that Defendants have "plans to vigorously pursue reversal of the district court decision and continued VASCEPA sales growth" and that "Amarin has confidence that we will create significant shareholder value." Thero also said:

> Regarding the district court ruling and the ANDA litigation, as previously communicated, we were surprised and disappointed that the court determined that patent, upon which we relied to build our business, should be considered invalid based upon arguments of perceived obviousness. In doing so, in my view, the court's decision not only did not fully appreciate the importance of VASCEPA as a unique and valuable breakthrough therapy, for which I believe there is considerable evidence, but it also overturned the decision of the U.S. Patent Office, which, earlier, had granted our patents after thorough review of prior arc and after its own consideration of obviousness.

Thero went on to say:

> Amarin is confident that we will find pathways to create value for its shareholders from our operations in the United States and internationally. We have overcome greater challenges in the past. Amarin is well capitalized. Our revenues grew over 100% in Q1 of 2020 compared to last year. We have great people. We have a unique product with unprecedented clinical results, and we are addressing a potentially huge market need.

188. After the District Court ruling, several analysts also spoke with Amarin's management and received further comfort regarding Amarin's patents for Vascepa

and the associated litigation. For example, J.P. Morgan's analysts wrote on March 30, 2020:

> We had the chance to catch up with AMRN mgmt and wanted to share a few points of feedback from our call.
>
> * * *
>
> Not surprisingly, Amarin intends to appeal. Obviously whether any of the generics would launch at-risk (once approved) while waiting for an appellate decision remains to be seen. In the meantime, mgmt will continue to execute on their plan to grow the market although they may not spend as much on DTC prior to clarity on the appeal as they view this as a long-term investment. Whether AMRN wins or loses on appeal, mgmt expects to ultimately be able to run the company profitably and sees potential competitive advantages in its manufacturing scale.

189. Similarly, on March 31, 2020, an analyst from Cantor Fitzgerald wrote: "We had a chance to catch up with AMRN this evening, and our key takeaway is that it's not game over yet. As expected, AMRN will appeal the ruling." Then, on April 2, 2020, Jefferies reported: "AMRN 'strongly disagrees' with the recent ruling and believes it is 'favorably situated' to win an appeal and restore US exclusivity out to 2030." And on April 13, 2020, SBV Leerink summarized: "Bottom Line: Management continues to feel strongly about its ability to win the Vascepa patent litigation upon an appeal, and hopes to accelerate trial timelines for oral arguments this summer."

190. Accordingly, the price of Amarin's ADSs remained inflated, with Defendants continuing to conceal the full impact of their fraudulent scheme from investors.

191. Then, on September 2, 2020, the U.S. Court of Appeals for the Federal Circuit held an oral argument for Amarin's patent litigation. The following day, the Federal Circuit affirmed the District Court's ruling. As the oral argument progressed and the Federal Circuit's ruling had become known to investors, Amarin's ADS share price fell approximately 40.77% to close at $4.30 per share on September 4, 2020, on heavy trading volume. The decline in Amarin's ADS price is in stark contrast to both the 5.25% drop in the NASDAQ Composite Index and 2.84% drop in the NASDAQ Biotechnology Index.

192. Analysts covering the Company could not ignore the direct impact these events had on the price of Amarin's ADSs. SBV Leerink reported on September 2, 2020: "Bottom Line: Overall, we don't believe this 3-judge panel improves Amarin's chances at winning the Vascepa patent litigation appeal, and the stock is down 15-20% on the news in early trading." SVB Leerink further reported later that day that Amarin's "stock is down ~30% following the oral arguments in the US appeals case." The analysts at SVB Leerink surmised this because "[t]he tone of the oral arguments, even to the non-legal ear, certainly suggests that the judges will not rule in Amarin's favor." That same day, a Jeffries analyst noted that "today's hearing in front of a three Judge panel did not go well." On September 2, 2020, SA news editor Douglas W. House similarly reported: "[A]rguments by attorneys representing the company are not going that well. Shares are down 27% on almost 7x higher volume 2 1/2 hours

into session." A few days later, on September 6, 2020, another SA analyst noted: "Amarin shares have taken a beating this week during the appellate hearing and especially after the adverse ruling came down on September 3." The results led Cantor Fitzgerald to decrease their price target for Amarin ADSs on September 8, 2020, explaining: "The decrease in our price target is driven by downward earnings estimate revisions for U.S. sales of Vascepa, post a negative appeal ruling."

193. However, instead of fully disclosing the truth, Defendants continued to reassure the market as to the viability of Vascepa's patents. For example, during Amarin's 3Q 2020 earnings call on November 5, 2020, Thero stated:

> As you know, we are very disappointed that the Federal Circuit upheld the District Court's earlier patent decision. On November 4, 2020, our rehearing and *en banc* petitions were denied. We plan within 90 days of such denial to ask the U.S. Supreme Court to hear our appeal. We believe that courts were wrong in their decisions, and we will continue to pursue this matter, although we cannot provide any guarantee of success in this pursuit.
>
> * * *
>
> The need for VASCEPA in the United States is large, and we aim to grow the market faster than generics companies can take meaningful market share due to anticipated generic manufacturing capacity limitations and associated time and cost for them to supply the market.

194. Thereafter, on April 12, 2021, after the market closed, Amarin announced the retirement of Thero (age 60). The same announcement noted Mikhail, Amarin's SVP and Head of Commercial for Europe, would succeed Thero as the Company's

next President and CEO. The press release noted the following relevant detail concerning Mikhail's background:

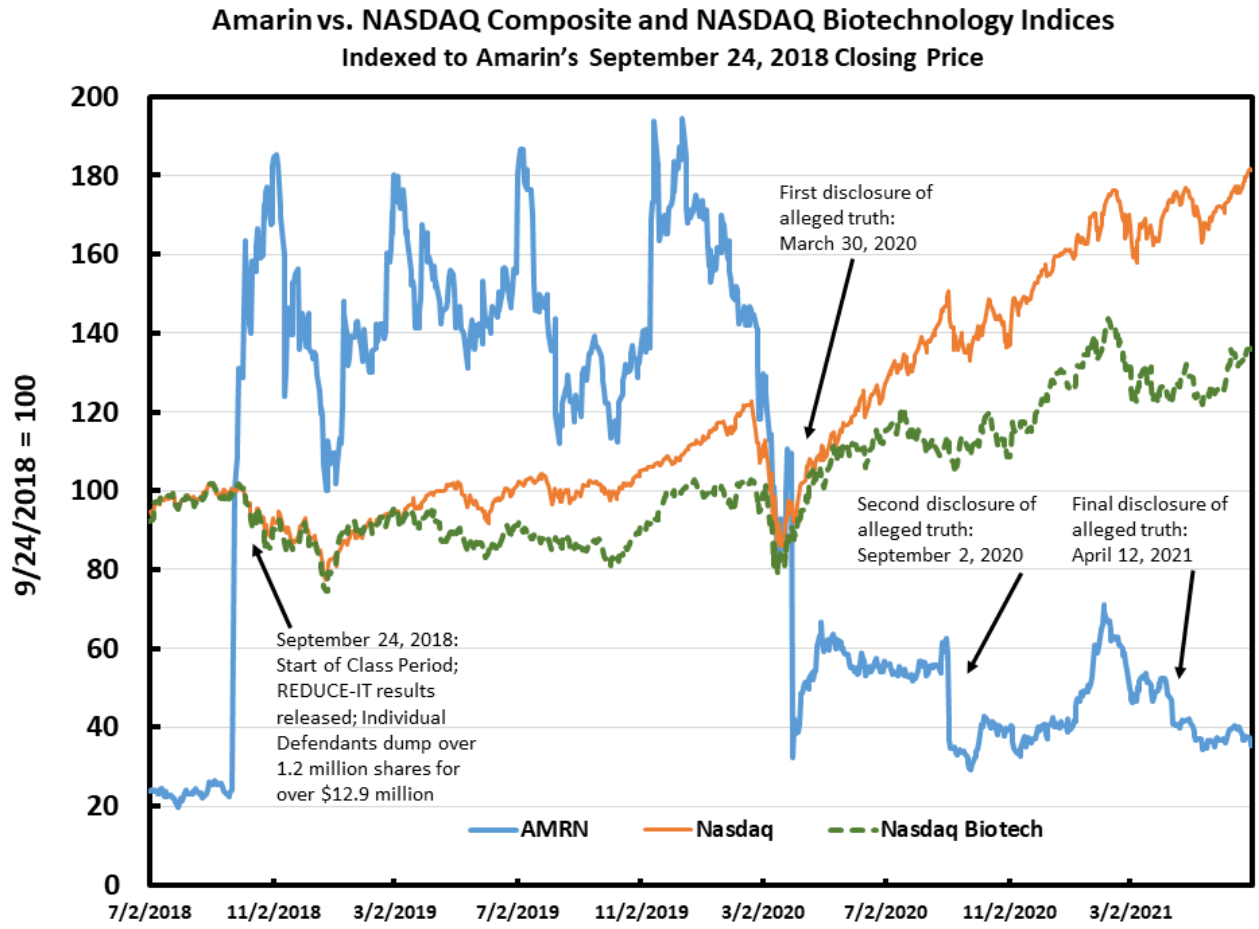
> ***Mr. Mikhail joined Amarin in 2020*** from THEODON, a global commercial strategy consultancy he founded in 2018. . . . Mr. Mikhail spent more than 20 years at Merck, where from 2014 to 2018 he served as global commercial leader for Merck's $4 billion lipid franchise, overseeing P&L and leading the worldwide launch of ezetimibe with the IMPROVE-IT study indication. In this role, ***he was responsible for reversing the business' decline in the U.S. market and globally***, accelerating revenue by an additional $380 million through the launch of ATOZET and driving EBITDA growth through international expansion. Prior to that, Mr. Mikhail led the successful commercial launch of dozens of products, including ezetimibe and various molecules in diabetes, hypertension, immunology, and oncology, and served as Merck's chief marketing officer for Europe, Middle East and Africa and chief operating officer for emerging markets. At Amarin, Mr. Mikhail has been responsible for preparing commercialization of the company's lead product in Europe, for which regulatory approval was received on March 30, 2021.

195. The decision to promote Mikhail, a specialist in foreign markets, to President and CEO demonstrated to investors that the Company and its senior management had decided to concede defeat in the U.S., where Vascepa's patents had been invalidated, and shift focus abroad. That day, Jeffries analysts wrote "the CEO transition announced today signals a tough road ahead for an EU launch that will naturally take time and patience." The replacement of Thero also demonstrates the Company held him responsible for Amarin's downfall in the U.S. As a SA analyst noted on April 13, 2021, this "strategic move could finally unlock the [C]ompany's

value" and Thero "must take responsibility for their legal failures, their underwhelming sales performance, and the share price."

196. On this news, the price of Amarin's ADSs fell by approximately 13.01% to close at $5.08 per share on April 13, 2021, on heavy trading volume. In comparison, the NASDAQ Composite increased by 1.05% and the NASDAQ Biotechnology index increased by 1.77%.

197. Each disclosure of adverse facts that removed inflation from Amarin's ADS price was connected to Defendants' material false statements and omissions and the fraudulent conduct alleged herein. The following chart demonstrates the clear divergence of Amarin's ADS prices from the overall market index (NASDAQ Composite) and its peer index (NASDAQ biotechnology) as the relevant truth became known to the market:



198. In sum, as detailed above, the rapid declines described herein served to remove the artificial inflation from the price of Amarin's ADSs, and were direct and foreseeable consequences of the revelation of the relevant truth concealed by Defendants about Vascepa and its patents.

IX. NO SAFE HARBOR

199. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the false and misleading statements pleaded in this pleading. None of the statements

complained of herein was a forward-looking statement. Rather, they were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including statements about data and information that Amarin had access to.

200. Amarin's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability because they were not accompanied by meaningful cautionary language. Given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Amarin were not sufficient to insulate Defendants from liability for their materially false and misleading statements.

201. Defendants are also liable for any false or misleading forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew the statement was false or misleading and was authorized and/or approved by an executive officer of Amarin who knew that the forward-looking statement was false.

X. AMARIN SECURITIES TRADED IN AN EFFICIENT MARKET

202. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;
- Amarin ADSs traded in an efficient market, was liquid and traded with moderate to heavy volume during the Class Period;
- the Company's ADSs were traded on the NASDAQ and were covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's ADSs; and
- Plaintiffs and members of the Class purchased, acquired, and/or sold Amarin ADSs between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

203. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

204. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed herein.

XI. CLASS ACTION ALLEGATIONS

205. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of the Class, consisting of all those who purchased or otherwise acquired Amarin ADSs during the Class Period and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are the Individual Defendants and their immediate families, the officers and

directors of the Company, at all relevant times, and members of their immediate families, legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

206. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Amarin ADSs were actively traded on the NASDAQ in an efficient market. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Amarin or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

207. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

208. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

209. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of Amarin;
- whether the Individual Defendants caused Amarin to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the price of Amarin ADSs during the Class Period was artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

210. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Defendants

211. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

212. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

213. Defendants violated §10(b) of the Exchange Act, 15 U.S.C. §78j(b) and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5, in connection with the purchase and sale of securities in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material fact and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class during the Class Period.

214. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members as alleged herein; (ii) artificially inflate and maintain the market price of Amarin ADSs; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Amarin ADSs at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

215. Pursuant to the above plan, scheme, conspiracy, and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Amarin ADSs. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Amarin's business practices.

216. By virtue of their positions at Amarin, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially

false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

217. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

218. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's ADSs during the Class Period, upon the disclosure of the facts alleged herein.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

219. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

220. During the Class Period, the Individual Defendants participated in the operation and management of Amarin, and conducted and participated, directly and indirectly, in the conduct of Amarin's business affairs. Because of their senior

positions, they knew the adverse non-public information about Amarin's business practices.

221. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Amarin's financial condition and results of operations, and to correct promptly any public statements issued by Amarin which had become materially false or misleading.

222. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Amarin disseminated in the marketplace during the Class Period concerning Amarin's results and operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Amarin to engage in the wrongful acts complained of herein. Amarin, in turn, controlled the Individual Defendants and all of its employees. The Individual Defendants, therefore, were "controlling persons" within the meaning of §20(a) of the Exchange Act, 15 U.S.C. §78t(a). In this capacity, they participated in the unlawful conduct alleged that artificially inflated the market price of Amarin ADSs.

223. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's ADSs during the Class Period, upon the disclosure of the facts alleged herein.

224. By reason of the above conduct, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act, 15 U.S.C. §78t(a).

COUNT III

For Violations of Section 20A of the Exchange Act Against the Individual Defendants

225. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

226. As detailed herein, the Individual Defendants were in possession of material non-public information concerning Amarin. The Individual Defendants took advantage of their possession of material non-public information regarding Amarin to obtain significant insider trading profits during the Class Period.

227. The Individual Defendants' sales of Amarin ADSs (set forth below and in the attached Appendix) were made contemporaneously with Plaintiffs' purchases of Amarin ADSs (set forth below and in Plaintiffs' certifications (Exhibits A and B)) during the Class Period.

228. Thero made the following sales of Amarin ADSs contemporaneously with the following Plaintiffs' purchases of Amarin ADSs:

Thero Sales			Plaintiffs' Purchases		
Date	**Amount**	**Price**	**Date**	**Amount**	**Price**
11/12/2018	5,000	$20.72	11/14/2018	187	$15.68
11/12/2018	222,158	$19.71	11/14/2018	80	$15.40
11/12/2018	136,422	$18.05			
11/12/2018	244,031	$19.03			
11/19/2018	274,454	$22.65	11/21/2018	311	$18.72

11/11/2019	41,741	$17.88	11/13/2019	1,934	$21.36
11/11/2019	433,805	$17.05	11/13/2019	2,835	$21.67
			11/13/2019	2,998	$21.51
			11/13/2019	4,683	$21.70
			11/13/2019	9,829	$21.53
			11/15/2019	1,486	$23.79
			11/15/2019	6,599	$23.07
			11/15/2019	14,697	$23.89
11/19/2019	274,454	$22.65	11/22/2019	281	$20.82

229. Kalb made the following sales of Amarin ADSs contemporaneously with the Pension Fund's purchases of ADSs:

Kalb Sales			**The Pension Fund's Purchases**		
Date	**Amount**	**Price**	**Date**	**Amount**	**Price**
9/24/2018	79,800	$10.15	9/27/2018	467	$13.82
9/24/2018	70,200	$10.72	9/27/2018	656	$14.14
			9/27/2018	3,510	$14.06
			9/27/2018	5,298	$14.09
			9/28/2018	8,923	$15.24

230. Kennedy made the following sales of Amarin ADSs contemporaneously with the following the Pension Fund's purchases of ADSs:

Kennedy Sales			**The Pension Fund's Purchases**		
Date	**Amount**	**Price**	**Date**	**Amount**	**Price**
9/24/2018	$10.27	884,800	9/27/2018	467	$13.82
9/24/2018	$12.14	139,706	9/27/2018	656	$14.14
9/24/2018	$11.14	55,200	9/27/2018	3,510	$14.06
			9/27/2018	5,298	$14.09
			9/28/2018	8,923	$15.24
10/1/2018	$17.99	8,400	10/4/2018	2,449	$19.19
10/1/2018	$17.47	8,800	10/4/2018	7,014	$19.93
10/1/2018	$16.33	33,049			

231. Plaintiffs and members of the Class who purchased shares of Amarin ADSs contemporaneously with sales by the Individual Defendants suffered damages because: (1) in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of §§10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder, as alleged herein; and (2) they would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the false and misleading statements and concealment alleged herein.

232. By reason of the above conduct, the Individual Defendants are liable pursuant to §20A of the Exchange Act, 15 U.S.C. §78t-1.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

DATED: January 13, 2023

SEEGER WEISS LLP

s/ *Christopher A. Seeger*

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on January 13, 2023, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to all counsel of record.

s/ *Christopher A. Seeger*
CHRISTOPHER A. SEEGER